
MassBiotech 2010

ACHIEVING GLOBAL LEADERSHIP IN
THE LIFE-SCIENCES ECONOMY



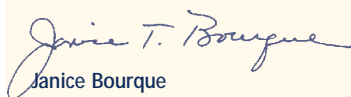
FOREWORD

Massachusetts can seize the opportunity to achieve global leadership in the life-sciences economy. The biotechnology industry will play a central role in enhancing human health while fueling economic growth. Together we can be successful in continuing scientific excellence and creating nearly 100,000 new jobs by 2010.

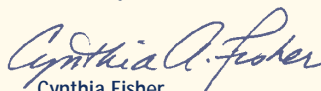
MassBiotech 2010: Achieving Global Leadership in the Life-Sciences Economy is the product of a three-month study involving representatives from over 100 diverse groups including biotechnology companies; universities and academic medical centers; pharmaceutical companies; and federal, state and local government leaders. The report articulates a vision for the Massachusetts biotechnology industry and the broader life-sciences economic cluster. It identifies the main challenges and presents a detailed call to action—for Massachusetts policymakers and for the life-sciences community.

We thank the many individuals who gave their time, energy, and ideas to create a report with both vision and depth. We acknowledge the significant contributions of the members of the MBC board, many of whom served as leaders on the steering committee and on the nine topic teams; The Boston Consulting Group for analytic rigor and professionalism in conducting research, coordinating interviews, and writing the final report; and the leaders of major life-sciences organizations who provided their perspectives on biotechnology and its role in the Massachusetts life-sciences economy. All individuals are listed by name in Appendix II of the report (starting on p. 59).

To achieve the vision by 2010, Massachusetts policymakers and biotech, academic, and medical leaders must work together. The Massachusetts Biotechnology Council is committed to the future of the Commonwealth's life-sciences economy and stands ready to make the vision a reality.



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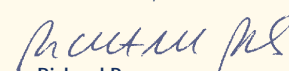
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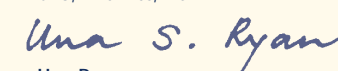
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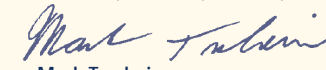
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ABOUT THE REPORT

MassBiotech 2010: Achieving Global Leadership in the Life-Sciences Economy is a joint report of the Massachusetts Biotechnology Council (MBC) and The Boston Consulting Group (BCG). A BCG team, headed by David Matheson and Martin B. Silverstein, M.D., conducted the research, coordinated the interviews, and captured the ideas and recommendations in the report. Mr. Matheson and Dr. Silverstein are senior vice presidents in the firm's Boston office and leaders in the firm's global health care practice. BCG consultants Robert Howard, Jeanine Kelly Murphy, Fabrice Paublant, Vikas Taneja, and Brooke Winkle made important contributions to the project.

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EXECUTIVE SUMMARY



The Massachusetts biotechnology industry is poised on the threshold of a new era of growth. It is far from clear, however, whether the state will capture the full benefits.

After more than two decades of innovation and investment, the Massachusetts biotechnology industry is poised on the threshold of a new era of growth. Breakthroughs in basic science at Massachusetts universities and academic medical centers are giving birth to a dynamic life-sciences economy and making the state a magnet for public and private investment in life-sciences research. The entrepreneurial energies of Massachusetts scientists and business people have made the state a leader in the global biotechnology industry. Currently, approximately 8 percent of the world's total pipeline of new drugs (pharmaceuticals as well as biotech) comes from companies headquartered in Massachusetts. This pipeline represents enormous potential for growth and job creation.

It is far from clear, however, whether Massachusetts will capture the full benefits of this growth. Competition for biotech jobs from other states is getting tougher. Massachusetts is behind in the race for regional advantage. Despite double-digit rates of growth and the arrival of major new employers in the state, the share of national biotech jobs located in Massachusetts has actually declined slightly in the past five years. And investment and venture-capital activity has been growing twice as fast in some of our key rivals as it has in Massachusetts.

If the state's political, business, and academic leadership does not respond, the Massachusetts biotech industry will continue to grow, but it will represent an ever diminishing share of biotech jobs. Alternatively, if the state mounts a concerted effort now, by 2010 the industry could expand its share of employment, create nearly 100,000 additional in-state jobs (approximately one third in biotechnology and two thirds in service and support industries), and raise more than \$1 billion in cumulative personal income tax revenues.

This report, a joint product of the Massachusetts Biotechnology Council (MBC) and The Boston Consulting Group (BCG), is a call to action. We call on political, business, and academic leaders to embrace the vision of making Massachusetts the most productive and most innovative place in the world for life-sciences companies to do business (see the sidebar "Our Vision" on p. 8). To realize this vision, the state must address four key challenges:

- Respond to the growing competition from other regions;
- Maintain the Massachusetts legacy of world-class research and innovation and become the best at converting research into commercial innovation;
- Extend the local biotechnology industry from its base in research to activities further down the value chain, such as development and manufacturing;
- Leverage the resources and networks of the broader life-sciences economic cluster of which biotechnology is an integral part.

In meeting these challenges, Massachusetts state government has a central role to play. We are sensitive to the constraints imposed by the current budget crisis, but we are convinced that much can be done at little or no direct cost to the treasury (see the sidebar “Ten Things the Governor and the State Legislature Can Do Immediately” on p. 9). We call on the governor and the state legislature to:

- *Champion the industry* and become a catalyst for biotechnology economic development;
- *Improve the business climate* by ensuring a streamlined framework for innovation and regulation;
- *Plan the next generation of biotech development* and work with interested local communities to speed the zoning and permitting process for new biotech facilities; and
- *Invest in strong science education*, so Massachusetts citizens can take advantage of the opportunities the life-sciences cluster will create.

It is equally important for the Massachusetts life-sciences community—universities, research institutes, hospitals, and companies—to organize itself for regional advantage and to extract maximum value from its network of relationships. We call on industry and academic leaders to:

- *Organize a clear leadership group* focused on the success of the life-sciences cluster as a whole;
- *Improve networking and collaboration* within the industry, between the industry and the academic community, and within the academic community;
- *Create a more efficient operating environment* by working together to address issues of shared interest such as technology transfer, clinical trials, and labor forecasting; and
- *Make a commitment to active public outreach* so the community at large is aware of the benefits of biotechnology and the life sciences and supports their further development.

The state’s political, commercial, and academic leaders need to move quickly and decisively to capture for Massachusetts the advantage that has already been created. If they can find a way to do so, the rewards for the Commonwealth could be substantial. They could well make the difference between a state that is enjoying a sustained period of strong economic growth and one that is merely limping along. The difference in tax revenues would be sizable. Perhaps most valuable, the Commonwealth could continue its honorable tradition of exercising global leadership on the frontiers of science, technology, and health care, and of producing enterprises of which its citizens are justifiably proud. The MBC and its member companies are committed to helping realize that vision.



The state’s political, commercial, and academic leaders need to move quickly and decisively to capture for Massachusetts the advantage that has already been created.

Massachusetts Biotech 2010: Our Vision

THE MASSACHUSETTS BIOTECH 2010 VISION IS FOR MASSACHUSETTS TO ACHIEVE GLOBAL LEADERSHIP IN THE BIOTECHNOLOGY INDUSTRY.

The goal is to develop better health care solutions, strengthen science excellence and education, and provide broad job opportunities. To realize this vision, the state of Massachusetts must:

- **Build** multiple vital partnerships within the life-sciences cluster,
- **Expand** the state's job base aggressively from research to development through manufacturing,
- **Retain** and support existing companies, and
- **Attract** new research investment at growth rates comparable to those in key competitive states.

The vision can be realized only if there is a substantially enhanced and active state role in biotech economic development, significantly enhanced patterns of collaboration within the Massachusetts biotechnology community and the broader life-sciences economic cluster of which it is a part, and greater public support for the industry.

Global leadership will enable Massachusetts to become:

- A provider of better health care solutions
- The most productive environment for biotech companies
- The leader in research and discovery
- An attractive location for development and manufacturing
- A model for comprehensive collaboration among industry participants
- Headquarters for several of the world's largest and fastest growing biotechnology companies
- The best place for students and professionals to study and innovate

Although the Massachusetts biotech industry during the past five years has grown 10 percent annually, has contributed half of net industrial job growth, and has attracted major new employers to the state, competing states have greater momentum. To capture the Massachusetts advantage, the state and the governor need to make a commitment to:

- Champion the industry,
- Improve the business climate by ensuring a streamlined framework for innovation and regulation,
- Plan for the next generation of biotech development,
- Invest in strong science education at all levels (kindergarten through post-graduate).

Realizing the vision will bring substantial economic benefit to the state. The Massachusetts biotechnology industry currently includes 280 firms and 30,000 employees. It is plausible that with the right conditions, the industry will by 2010 create nearly 100,000 new in-state jobs (one third in biotechnology and two thirds in service and support industries), raise more than \$1 billion in cumulative personal income tax revenues, and make a critical contribution to the economy's growth.



Ten Things the Governor and the State Legislature Can Do Immediately

1. Reinstatement of the position of secretary of economic affairs with a mandate and the resources to capture economic-development opportunities in the life sciences.
2. Appoint a science and technology senior advisor who is respected by the life-sciences cluster and aware of the challenges it faces. The senior advisor should report directly to the governor and steer the key initiatives undertaken by the new administration.
3. Introduce and support legislation (including legislation on stem-cell research and biodefense) that will enable life-sciences organizations to operate and innovate within a clear and predictable framework.
4. Work with industry, public agencies, and local communities to identify promising sites for future biotech development, streamline the permitting process, and plan the physical infrastructure.
5. Establish a science education advisory board to define the priorities, identify curriculum synergies across the state's different school systems, and initiate changes at all levels of education.
6. Make a commitment to stabilize the tax environment and make the investment tax credit permanent at 3 percent.
7. Change the legal definition of an R&D corporation and file appropriate legislation to ensure that all life-sciences start-ups can benefit from the status.
8. Encourage state pension funds and other public investment funds to invest in start-ups and early-stage venture capital funds.
9. Promote collaboration initiatives among public universities, public agencies, and the industry, in particular on homeland-security issues.
10. Communicate broadly and often about the importance of biotechnology to the state in order to create positive perceptions of biotechnology in the minds of decision makers and the public.



MassBiotech 2010

Report



INTRODUCTION

By any measure, Massachusetts is at the heart of the global biotechnology industry. Massachusetts universities and academic medical centers have been a remarkable engine of innovation in a critical new science that is having an enormous impact on health care and the quality of people's lives. Massachusetts researchers and entrepreneurs have created what, at some 280 firms and 30,000 employees, is one of the largest regional concentrations of biotech companies in the world. Not only has Massachusetts become the headquarters of some of the leading companies in the industry; it has also become a magnet for investment by other companies that want to participate in the state's dynamic life-sciences economy. In the past ten years, many of the world's largest pharmaceutical companies, attracted by the state's entrepreneurial environment and critical mass of companies, universities, and hospitals, have established basic research facilities in Massachusetts.

The state and its economy have benefited from this global leadership. During the past five years, employment in the biotech industry has grown 10 percent annually and has contributed roughly half of the new industrial jobs in Massachusetts. Today, biotechnology accounts for 18 percent of the state's venture-capital investment, 27 percent of its R&D spending, one sixth of its public companies, and approximately 10 percent of its market capitalization. What's more, the fact that approximately 8 percent of the world's pipeline of new medications (pharmaceuticals as well as biotech) is now located in Massachusetts represents enormous potential for growth and job creation.

It is far from certain, however, that Massachusetts will capture the full benefit of these developments. Competition for biotech jobs is getting tougher as rival states such as California and North Carolina, often with strong state-government support, organize to attract companies and jobs. These states recognize that in addition to the typical competitive battles between companies and institutions, there is an emerging competitive struggle among regions. Currently, Massachusetts is not organized to compete in this race for regional advantage. Despite double-digit rates of growth, the share of total U.S. biotech jobs located in Massachusetts has actually declined slightly in the past five years.

At the same time, the Massachusetts biotech companies founded in the early 1990s are beginning to shift their emphasis from research and discovery to development, manufacturing, and commercialization. This is where the lion's share of future economic value—and future jobs—will be generated. It is also where Massachusetts has traditionally been most disadvantaged.

If the state's political, business, and academic leadership does not respond, the Massachusetts biotech industry will continue to grow, but it will represent an ever diminishing share of the industry's jobs. Alternatively, if the state mounts a concerted effort now, by 2010 the Massachusetts industry could expand its share of biotech employment, create nearly 100,000 additional in-state jobs (approximately one third in biotechnology itself and two thirds in indirect service and support industries), and raise more than \$1 billion in cumulative personal income tax revenues.



Not only has Massachusetts become the headquarters of some of the leading companies in the biotech industry; it has also become a magnet for investment by other companies that want to participate in the state's dynamic life-sciences economy.

This conclusion is the product of a three-month study of the Massachusetts biotechnology industry and the broader life-sciences economic cluster of which it is a part. The study was conducted by the Massachusetts Biotechnology Council (MBC) and The Boston Consulting Group (BCG).

We interviewed more than 60 CEOs and senior executives in biotech companies, pharmaceutical research organizations, universities, hospitals, and government. We built an economic model to forecast industry growth under a variety of scenarios. We also worked closely with nine MBC topic teams, with representatives from some 50 institutions, to develop recommendations in areas such as business climate, work-force education, tax policy, and regulatory policy (for a complete list of topic team recommendations, see Appendix I, p. 49). Finally, we helped create a cross-industry advisory committee made up of the leaders of 20 top life-sciences institutions in Massachusetts. All told, more than 100 institutions—companies, universities, academic medical centers, venture capitalists, state and local government, etc.—have participated in our study (for a complete list of participants, see Appendix II, p. 59).

This report is organized in seven sections:

- I. *Biotechnology and Its Role in the Massachusetts Economy:* In this section, we describe the social and economic contributions of biotechnology to the Massachusetts economy. The section includes BCG's economic analysis of the industry and estimates of its growth potential.
- II. *The Race for Regional Advantage:* Massachusetts is clearly behind in the race for regional advantage. Other regional centers have stronger support from their state governments and are better organized internally to compete for new growth and new jobs. In this section, we argue that Massachusetts cannot afford to ignore these competitive threats.
- III. *Maintaining World-Class Research and Innovation:* World-class research is the critical source of competitive advantage for Massachusetts. It is important not to take it for granted. Despite its extraordinary strength over the last decades, there are some emerging signs of potential weakness. In this section, we argue that Massachusetts institutions must organize to convert our unusually rich research base into commercial innovations and opportunities.
- IV. *Moving Down the Drug-Development Value Chain:* Local biotechs have been systematically growing from their base in research into development, manufacturing, and commercialization. About 60 Massachusetts biotech companies currently have products in the development pipeline. Although Massachusetts has always been an attractive environment for research, it is not well organized to support activities further down the value chain. In this section, we argue that from the perspective of state economic development, this is a worrisome trend. Not only do downstream jobs allow the state to spread the benefits of biotech employment to a far broader segment of society, they also serve as an important anchor for keeping upstream jobs in the state.

- V. *Leveraging the Life-Sciences Economic Cluster:* Increasingly, biotechnology is an integral part of a much broader life-sciences economic cluster, which currently represents a full 13 percent of total state employment. In this section, we argue that the future success of both the biotechnology industry and the cluster as a whole will depend on improving the frequency and quality of interactions among cluster members. Increased collaboration and networking will enhance the innovation and productivity of each of the cluster's individual segments and broaden the opportunities for the kind of cross-fertilization that drives research innovation and creativity.
- VI. *The Role of State Government:* Meeting these challenges will require leadership. State government, in particular, needs to play a far more active and thoughtful role in mobilizing economic development in the life sciences. It can do so without placing substantial demands on the state treasury and without sacrificing legitimate and important public interests such as environmental protection. In this section, we describe how the state government can become a champion of and catalyst for biotech economic development, improve the business climate and the regulatory framework in which biotech and other life-sciences companies operate, plan the state's physical infrastructure to accommodate the next generation of biotech development, and invest in work-force development and K-12 science education so Massachusetts citizens can take advantage of the opportunities the life-sciences cluster creates.
- VII. *The Role of the Life-Sciences Community:* It is equally important for the Massachusetts life-sciences community to organize itself for regional advantage and to extract maximum value from its network of relationships. In the final section of the report, we argue that the life-sciences community must exercise clear leadership, invest in new mechanisms for increased networking and collaboration, create a more efficient and more integrated operating environment, and make a commitment to active public outreach.

Capturing the advantage of biotech economic development for Massachusetts won't happen overnight. It will require the concerted efforts of the political, business, and academic leadership of the state. The goal should be nothing less than to make Massachusetts the most innovative and productive environment in the world for life-sciences companies, and a leader in the development and commercialization of new therapies to improve health care.¹ We possess perhaps the greatest constellation of local advantages and pure human talent in the world. As one industry leader told us, "No place on the planet should be more attractive to a person going into life sciences." The challenge, however, will be to organize those advantages and talent to extract the maximum value. The state and its political, commercial, and academic leadership should act collectively to meet that challenge.



The goal should be nothing less than to make Massachusetts the most innovative and productive environment in the world for life-sciences companies, and a leader in the development and commercialization of new therapies to improve health care.

¹In the past year, the presidents of two distinguished Massachusetts universities, Harvard and MIT, have articulated a similar vision. See the comments of Lawrence Summers in Steve Bailey, "Silicon Valley II?" the *Boston Globe*, January 4, 2002, p. D1, and Charles M. Vest, "Genome Research Presents Opportunity for Hub," the *Boston Globe*, August 11, 2002, p. E4.

BIOTECHNOLOGY AND ITS ROLE IN THE MASSACHUSETTS ECONOMY



Today, there are some 280 biotech companies in Massachusetts, more than three times the number ten years ago.

Biotechnology combines an advanced understanding of living systems (from DNA in cells, to entire organisms, to the biological systems in the environment) with advanced technological tools to treat previously untreatable diseases, improve patients' quality of life by providing better treatment therapies, and offer innovative solutions to a variety of diagnostic, agricultural, and environmental challenges that exist today. (See the sidebar "The Public Benefits of Biotechnology").

Massachusetts has a unique set of strengths that have made it one of the world's leading centers of the biotechnology industry. The state's world-renowned universities and medical centers provide strong partners for basic research. The state's history of entrepreneurship and commerce has made it a breeding ground for new biotech companies that have already brought some 40 new products to market, including drugs, biodevices, and diagnostic tests (for a selective list of Massachusetts biotech products approved by the U.S. Food and Drug Administration (FDA), see Exhibit 1 on p. 16). The state's well-educated work force has provided a strong pool of employees. And the Massachusetts venture capital industry and legal and technological communities have provided important financial support and expertise. All these strengths have made it possible for the Massachusetts biotech industry to grow with dramatic speed over the past decade.

Today, there are some 280 biotech companies in Massachusetts, more than three times the number ten years ago. Approximately 230 of these companies were founded in Massachusetts. The rest are out-of-state institutions that have been drawn by the dynamism of the state's life-sciences economic cluster. In the past ten years, many of the world's largest pharmaceutical companies, including Abbott, AstraZeneca, Merck, and Pfizer, have chosen to locate research facilities in the state. Just last September, the Swiss-based pharmaceutical giant Novartis announced plans to locate its global research headquarters in Cambridge.

Spurred by this growth, employment in biotech has grown at an annual rate of 10 percent from about 18,000 people in 1996 to approximately 30,000 in 2001—the vast majority located in the Cambridge-Worcester corridor (see Exhibit 2 on p. 17).² Roughly three-fourths work at Massachusetts-founded companies, while one-fourth work for out-of-state companies. The industry's 60 public companies make up 17 percent of public companies in Massachusetts. And these companies generated \$6.7 billion in revenues in 2001, 3.5 percent of the \$190 billion generated by all Massachusetts public companies.

²This number includes biotech and pharmaceutical jobs, as well as jobs at related specialized suppliers such as lab supplies and equipment companies, clinical research organizations, and bioinformatics companies.

The Public Benefits of Biotechnology

AS IMPORTANT AS THE MASSACHUSETTS BIOTECH INDUSTRY IS TO THE ECONOMY AND GROWTH OF THE STATE, THE REAL PUBLIC BENEFIT OF BIOTECHNOLOGY IS THE PROMISE IT HOLDS TO DIAGNOSE AND TREAT MILLIONS OF PATIENTS NOT JUST IN MASSACHUSETTS BUT AROUND THE WORLD.³

As of 2001:

- More than 325 million people worldwide benefited from the more than 130 biotech drug products and vaccines approved by the FDA. These products treat disorders ranging from arthritis, asthma, and Alzheimer's disease to cancer, heart disease, and multiple sclerosis.
- More than 350 biotech drug products and vaccines, aimed at treating more than 200 diseases, are currently in clinical trials.
- Hundreds of diagnostic tests have been developed through biotechnology for uses ranging from screening blood for the AIDS virus to home pregnancy testing.
- The production of safe, nutritious foods is already being supported by biotechnology with crops such as disease-resistant soybeans and corn
- Industrial and environmental uses of biotechnology include enzymes that replace harmful chemicals in manufacturing or bacteria that eliminate toxic wastes.
- DNA fingerprinting, a biotech process, has dramatically improved criminal investigation and forensic medicine, as well as afforded significant advances in anthropology and wildlife management.
- Biotechnology is one of the most research-intensive industries in the world. The U.S. biotech industry spent \$15.6 billion on research and development in 2001.
- The biotech industry is regulated by the FDA, the Environmental Protection Agency (EPA), and the U.S. Department of Agriculture (USDA).



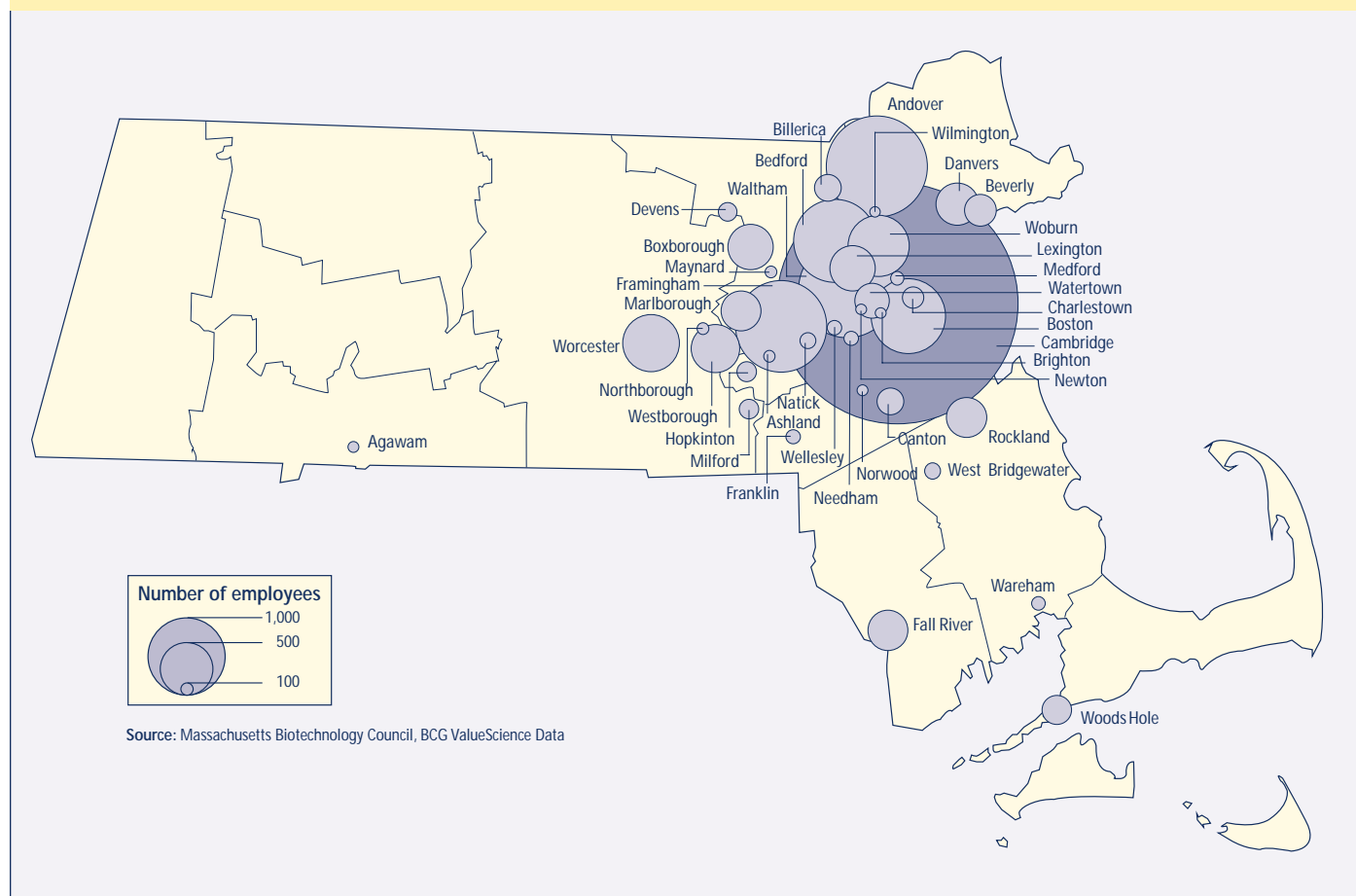
³The information in this sidebar is from "Some Facts About Biotechnology/Industry Statistics, 1993-2001," <http://www.bio.org/er/statistics.asp>, and "Biotechnology: A Guide to Understanding Investments That Make a Difference," Massachusetts Biotechnology Council, advertising supplement to the *Boston Globe*, October 16, 2002.

EXHIBIT 1: SELECTED LIST OF FDA-APPROVED MASSACHUSETTS BIOTECHNOLOGY PRODUCTS

COMPANY	PRODUCT	USED FOR
Abiomed	BVS-5000	Cardiac assistance for patients with failing hearts
Anika Therapeutics/ Staar Surgical	Staarvisc II	Ophthalmic surgeries
Biogen, Inc.	Avonex®	Multiple sclerosis
Biogen, Inc./ Schering Plough	Intron A®	Hairy cell leukemia Malignant melanoma Follicular lymphoma Genital warts AIDS-related Kaposi's sarcoma Chronic hepatitis B and C
Biopure Corporation	Oxyglobin®	Anemia (veterinary)
Curis, Inc./ Stryker Corporation	OP-1™ Implant	Bone fractures and defects
DUSA Pharmaceuticals/ Berlex	Levulan	Actinic keratoses, skin lesions (photodynamic therapy)
Exact Sciences	PreGen-26™	Detection of colorectal cancer
Genentech, Inc./ Alkermes, Inc.	Nutropin Depot™	Pediatric growth hormone deficiency
Genzyme Corporation	Carticel™	Articular cartilage injuries
Genzyme Corporation	Ceredase®/Cerezyme®	Type 1 Gaucher disease
Genzyme Corporation	Renagel®	Hyperphosphatemia in end-stage renal disease
Genzyme Corporation	SepraFilm®	Antiadhesion in surgery
Genzyme Corporation	Synvisc®	Osteoarthritic knee pain
Genzyme Corporation	Thyrogen®	Thyroid cancer (thyroid stimulating hormone)
Genzyme Corporation	Welchol®	LDL cholesterol
GTC Biotherapeutics/ Fresenius	Recombinant Human Serum Albumin	Blood disorders
The Medicines Company	Angiomax®	Coronary thrombosis (during or after angioplasty)
Millennium Pharmaceuticals, Inc./ ILEX Oncology, Inc.	Campath®	B-cell chronic lymphocytic leukemia
Millennium Pharmaceuticals/ Schering Plough	Integrilin	Acute coronary syndrome
Organogenesis, Inc./ Novartis	Apligraf®	Diabetic foot ulcers, venous leg ulcers
Sepracor, Inc.	Xopenex®	Asthma
Serono, Inc.	Gonal-F®	Infertility
Serono, Inc.	Rebif®	Multiple sclerosis
Serono, Inc.	Saizen®	Pediatric growth hormone deficiency
Serono, Inc.	Serostim®	AIDS wasting
Vertex Pharmaceuticals Inc./ GlaxoSmithKline, Inc.	Agenerase®	AIDS/ HIV
Wyeth	BeneFIX®	Hemorrhagic episodes (associated with Hemophilia B)
Wyeth	Neumega®	Low platelet counts (chemotherapy)
Wyeth	ReFacto®	Hemophilia A

Although biotech's 30,000 employees represent only about 1 percent of the roughly three million total jobs in Massachusetts, and 2 percent of total payroll, these numbers disguise the true importance of biotechnology to the state economy. For example, biotechnology is responsible for 5 percent of all industrial jobs in the state and accounted for about half of the net growth in such jobs between 1996 and 2001.⁴ During this five-year period the number of industrial jobs in Massachusetts grew from 667,000 to 691,000, a net increase of 24,000 jobs. Biotechnology represented 12,000 jobs, or half, of that increase (see Exhibit 3 on p. 19).

EXHIBIT 2: GEOGRAPHIC DISTRIBUTION OF MASSACHUSETTS BIOTECHNOLOGY EMPLOYMENT, 2001



Cambridge remains the geographic center of the industry, but more and more companies are locating in other Massachusetts communities.

⁴Industrial jobs, as opposed to service jobs, include all jobs at commercial enterprises in sectors such as manufacturing, construction, transportation, and utilities.



The Massachusetts biotechnology industry has laid the foundation for what should be significant job growth in the future.

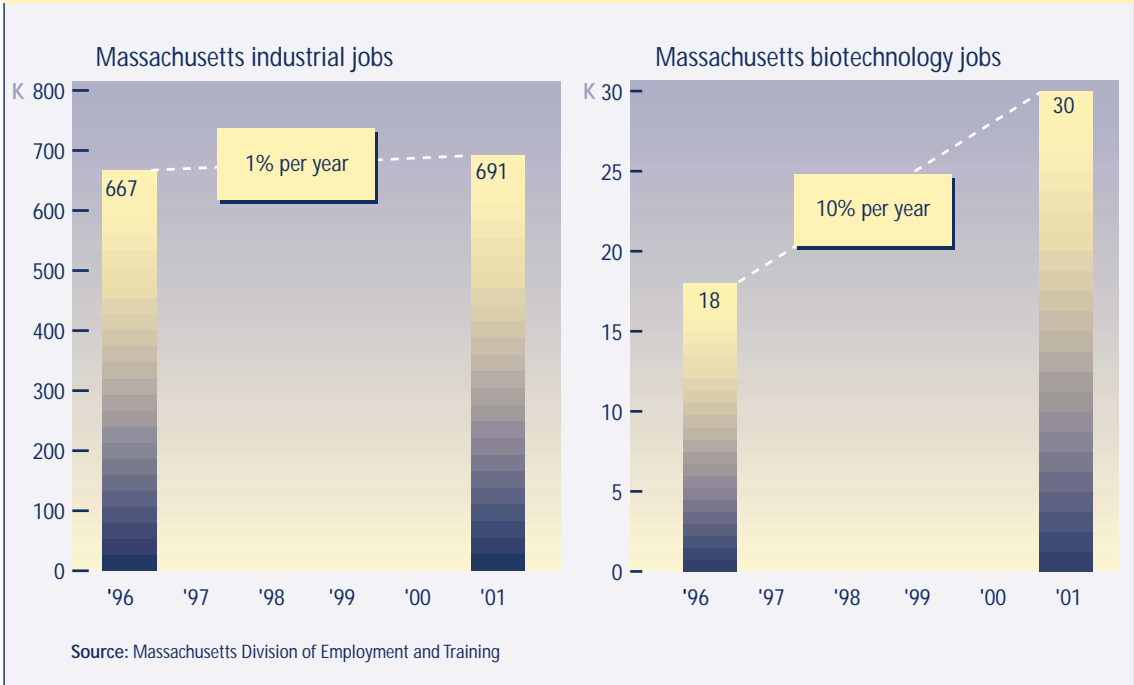
What's more, it has been estimated that for every direct job created by biotechnology, roughly two additional indirect jobs are created in support services such as business supplies and legal services and in related consumer spending.⁵ Taking this multiplier into account, the biotech industry is responsible for roughly 90,000 jobs in Massachusetts today. And the addition of millions of square feet of biotech lab and office space since 1991 in communities such as Cambridge, Boston, Waltham, Framingham, Woburn, and Worcester has been responsible for many temporary jobs in construction and real estate development as well.

The Massachusetts biotechnology industry has also laid the foundations for what should be significant job growth in the future. Since the mid-1990s, biotech research and development spending has increased by 22 percent, venture capital investment by 21 percent, and the number of biotech patents filed by 16 percent (see Exhibit 4 on p. 19). In 2001, the local biotech industry was responsible for 27 percent of the \$8.5 billion spent by Massachusetts public companies on research and development, 15 percent of the venture capital funds raised, and 18 percent of the patents filed. And from the number of compounds in clinical trials, we estimate that approximately 8 percent of the world's biotech and pharmaceutical pipeline is being developed by companies based in Massachusetts (see Exhibit 5 on p. 20, and the sidebar "Massachusetts 'Teenage' Biotechs: High Potential, Big Vulnerabilities" on p. 21). These numbers are important because they represent an investment in the future—an investment that, if managed carefully, will fuel industry growth and job creation.

The real question for the state's political and commercial leaders is: how many of those jobs will be located in Massachusetts? The answer depends on the perceived attractiveness of the state as a location for activities at each step of the biopharmaceutical value chain. We estimate that a concerted effort to capture these jobs for Massachusetts could produce approximately 100,000 additional jobs (see the sidebar "Modeling Biotech's Job-Creation Potential" on p. 22). To reach that goal, however, the state must address four fundamental challenges. We address these in detail in the next four sections of the report.

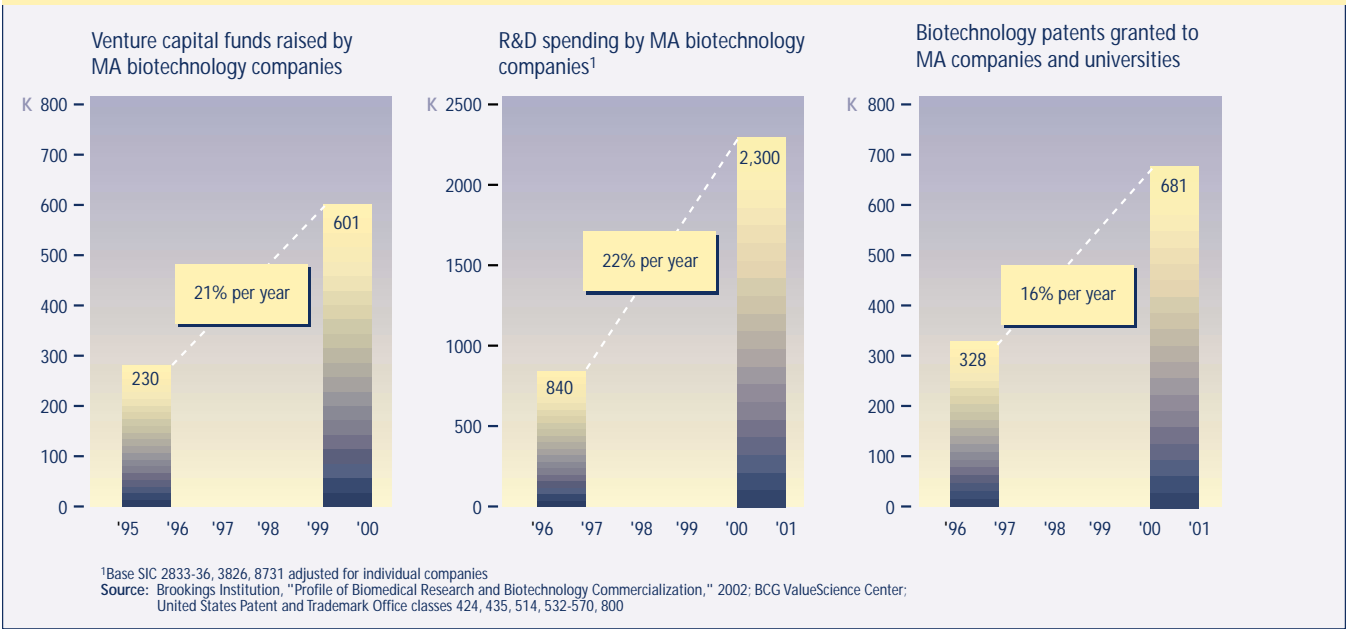
⁵See "Economic Contributions of the Biotech Industry to the U.S. Economy," prepared by Ernst & Young for the Biotechnology Industry Organization (BIO), May 2000.

EXHIBIT 3: MASSACHUSETTS INDUSTRIAL JOB GROWTH, 1996-2001



Biotech job growth in the state is outpacing total industrial job growth tenfold.

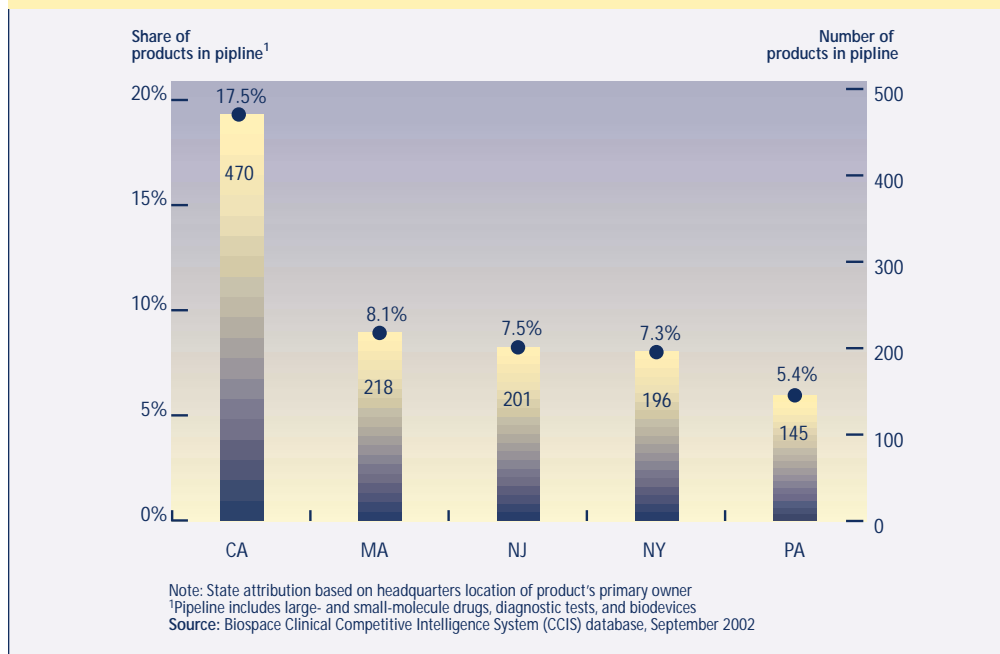
EXHIBIT 4: BIOTECHNOLOGY’S DOUBLE-DIGIT GROWTH IN INVESTMENT AND INTELLECTUAL CAPITAL



Biotechnology has experienced double-digit growth in venture capital investment, R&D spending, and new patents.



Massachusetts-based companies are responsible for approximately 8 percent of the potential drugs in the clinical-development pipeline, more than the companies of any other state except California.

EXHIBIT 5: LEADING STATES' SHARE OF GLOBAL CLINICAL-DEVELOPMENT PIPELINE


Massachusetts “Teenage” Biotech: High Potential, Big Vulnerabilities

THE NEXT FEW YEARS WILL BE CRUCIAL FOR THE MASSACHUSETTS BIOTECH INDUSTRY. AN UNPRECEDENTED WAVE OF NEW PRODUCTS WILL BE READY FOR LAUNCH. BUT MOST OF THE COMPANIES THAT HAVE DEVELOPED THESE PRODUCTS ARE LIKELY TO EXPERIENCE SEVERE FINANCIAL CONSTRAINTS.

They are a bit like adolescents—well beyond the infancy of their start-up years but not yet adults (in the sense of being healthy, profitable companies). More than a decade of innovation and investment is ready to come to fruition. Currently, 57 local biotech companies have 180 products in clinical development. The majority of these products are drugs, but more than a third are vaccines and biodevices. Applying current standard success ratios and time-to-market estimates for products in clinical development, the number of Massachusetts products on the market is poised to more than double from 40 today to 90 by 2005 (see Exhibit 6), a number matched only by California and New Jersey.

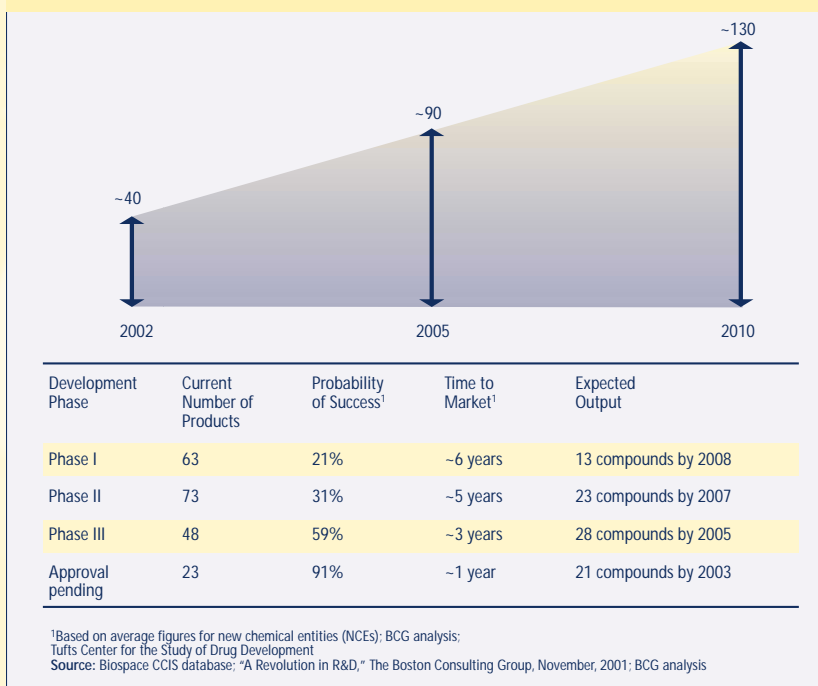
Unfortunately, many of the companies that own these products are highly vulnerable financially. Over 80 percent of the compounds in the pipeline are owned by small, not yet profitable companies. Only three of the 38 public companies with products in the pipeline have a positive cash flow. Even more worrisome, roughly half of the not yet profitable companies, together accounting for a third of the pipeline, will need additional capital within the next two years. As one executive put it: “Our biggest potential obstacle—besides bad luck—is lack of access to capital.”

These “teenage” companies are especially vulnerable in the current environment. Not only must they cope with the usual scientific and commercial risks associated with clinical development, they face increasing market risks as competition intensifies and as the reluctance of health care payers to cover expensive treatments grows. And financial risks are extremely high given that for the past year, financial markets have been largely closed to biotech initial public offerings (IPOs).

If the teenage companies stay independent and reach adulthood, Massachusetts will enjoy a significant number of new manufacturing, commercial, and construction jobs. Once a company obtains market approval for a product, it must quickly ramp up manufacturing, marketing, sales, and support functions in order to get to peak sales as quickly as possible.

But the financial vulnerability of many of these companies, coupled with the difficult financing environment, means that consolidation is likely to occur in the next few years. This expected merger-and-acquisition trend is both an opportunity and a threat for the state. If the local business environment is attractive, new owners could use their acquisitions to locate more activities in-state. Alternatively, if acquirers feel that other sites could do the job faster and cheaper, they might quickly decide to move most strategic activities out of state.

EXHIBIT 6: EXPECTED GROWTH OF FDA-APPROVED MASSACHUSETTS BIOTECHNOLOGY PRODUCTS, 2002-2010



Modeling Biotech's Job-Creation Potential

TO ASSESS BIOTECH'S CONTRIBUTION TO THE STATE ECONOMY, WE DEVELOPED AN ECONOMIC MODEL TO FORECAST THE LIKELY FUTURE IMPACT OF THE INDUSTRY ON JOB CREATION AND STATE TAX REVENUES.

We analyzed five key industry segments: Massachusetts biotechs with products in clinical development; early-stage start-ups without products in clinical development; companies that are not involved in drug development (for example, diagnostic and biodevice companies and agricultural biotech); specialized suppliers such as clinical research organizations, lab supply companies, and bioinformatics companies; and out-of-state companies with existing in-state facilities and potential new entrants.

We estimated the likely growth rate of each segment and its gross job-creation rate, using a combination of historical performance, market forecasts, the status of the product pipeline, and the current likelihood that jobs from the segment would be located in Massachusetts. Finally, we applied the industry-accepted 2-for-1 multiplier (see p. 18) to estimate the indirect jobs generated by biotech growth. This provided our base line.

Next, we developed three scenarios based on the attractiveness of Massachusetts as a location for jobs at each step in the drug discovery value chain. The first scenario, which we have called "Lose Ground," assumes that the attractiveness of Massachusetts as a location for biotech employment will continue to erode, in relation to rival clusters, leading to a continued decline of the state's share of national biotech employment. Under this scenario for example, only 50 percent of new R&D jobs and 25 percent of new manufacturing and headquarters jobs generated by local biotech companies would be located in the state.⁶

The second scenario, "Increase Share," assumes that Massachusetts captures roughly 75 percent of the new jobs in R&D and 50 percent of new manufacturing jobs. And the third scenario, "Unleash Potential," assumes that the state captures nearly all of locally generated new R&D and headquarters jobs and 75 percent of new manufacturing jobs (see Exhibit 7 for the results of this modeling exercise).

Notice that under all three scenarios, Massachusetts would experience net job growth. This is due to the overall growth of

the industry and the strength of its current pipeline. The range of this gain, however, varies by a factor of seven—from 20,000 additional jobs in the Lose Ground scenario to roughly 150,000 in the Unleash Potential scenario. The middle scenario, Increase Share, forecasts a doubling of the size of the biotech industry and the net creation of nearly 100,000 additional jobs.

Roughly one third of these new jobs created would be biotech industry jobs—half in research and development, a quarter in manufacturing, and the remaining 25 percent in commercial, marketing, management, and support. The remaining two thirds are indirect jobs in services and industries that serve the biotech companies and their employees.

We also estimated the potential tax revenues generated by the three scenarios. We focused on personal income tax revenues from the direct and indirect jobs, as these dwarf any corporate income tax revenues. The range of outcomes for the state budget is also significant. The Increase Share scenario would mean an additional \$1.1 billion in tax revenues by 2010, compared with the Lose Ground scenario. Achieving the Unleash Potential scenario would mean an additional \$1.9 billion (see Exhibit 8 for a summary of the tax and job effects for each scenario).⁷

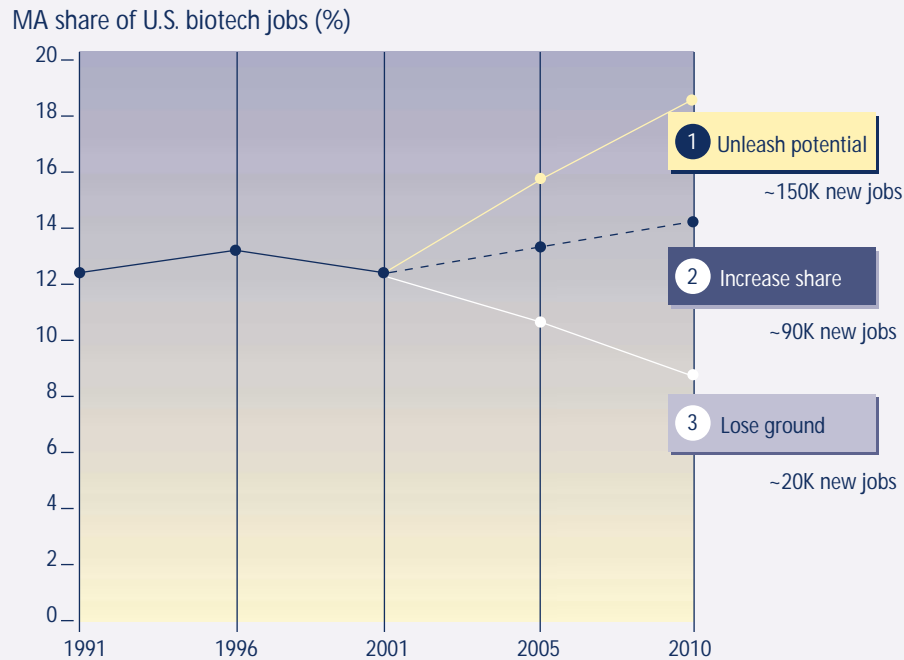


⁶These percentages are for drug-development companies and are based on historical location data; smaller percentages apply to other segments because of their smaller historical location bias.

⁷For additional details about the BCG economic model, see <http://www.massbiotech2010.com>.

EXHIBIT 7: THREE SCENARIOS FOR MASSACHUSETTS BIOTECH EMPLOYMENT GROWTH

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Sources: Ernst & Young, "The Economic Contributions of the Biotechnology Industry to the U.S. Economy," prepared for the Biotechnology Industry Organization (BIO), May 2000; Massachusetts Biotechnology Council, 2002 survey; BCG analysis

Depending on the attractiveness of the Massachusetts business environment, biotechnology could be responsible for anywhere from 20,000 to 150,000 new jobs by 2010.

EXHIBIT 8: THE IMPACT OF THE THREE SCENARIOS ON EMPLOYMENT AND TAX REVENUES

	2002 baseline	2010 SCENARIOS		
		1 Lose ground	2 Increase share	3 Unleash potential
Total MA Biotech jobs	30K	36.5K	60K	78K
Share of U.S. biotech jobs	12.1%	8.7%	14.2%	18.5%
New MA biotech jobs	—	6.5K	30K	48K
New MA indirect jobs ¹	—	~13K	~60K	~100K
New MA biotech and indirect jobs ¹	—	~20K	~90K	~150K
Yearly personal income tax ²	~\$300M	~\$350M	~\$580M	~\$750M
Cumulative personal income tax collected 2003-2010 ²	\$2.4B	\$2.7B	\$3.7B	\$4.5B

¹Using 2-for-1 multiplier ²Based on estimated wages in 2002 U.S.\$ from biotech and indirect jobs, taxed at current tax rates
Source: BCG analysis; BIO 2000 survey

THE RACE FOR REGIONAL ADVANTAGE



A key reason for the state's declining relative position is the recognition by other states that biotechnology economic development is, in large part, a race for *regional advantage*.

Depending on the precise criteria one chooses, the Massachusetts life-sciences cluster is either the largest or second largest in the world, with the San Francisco Bay Area its closest rival. But other regions are clearly gaining. For example, investment and venture capital activity in the life sciences has been growing twice as fast in our top five regional rivals as it has in Massachusetts (see Exhibit 9).

A key reason for the state's declining relative position is the recognition by other states that biotechnology economic development is, in large part, a race for *regional advantage*.⁸ In addition to the fight for competitive advantage among individual companies, there is a fight for advantage among regional networks of companies. And in these regional networks, nonindustry players such as state government, local academic institutions, venture capital networks, and the like are as important to the success of the industrial network as the companies themselves.

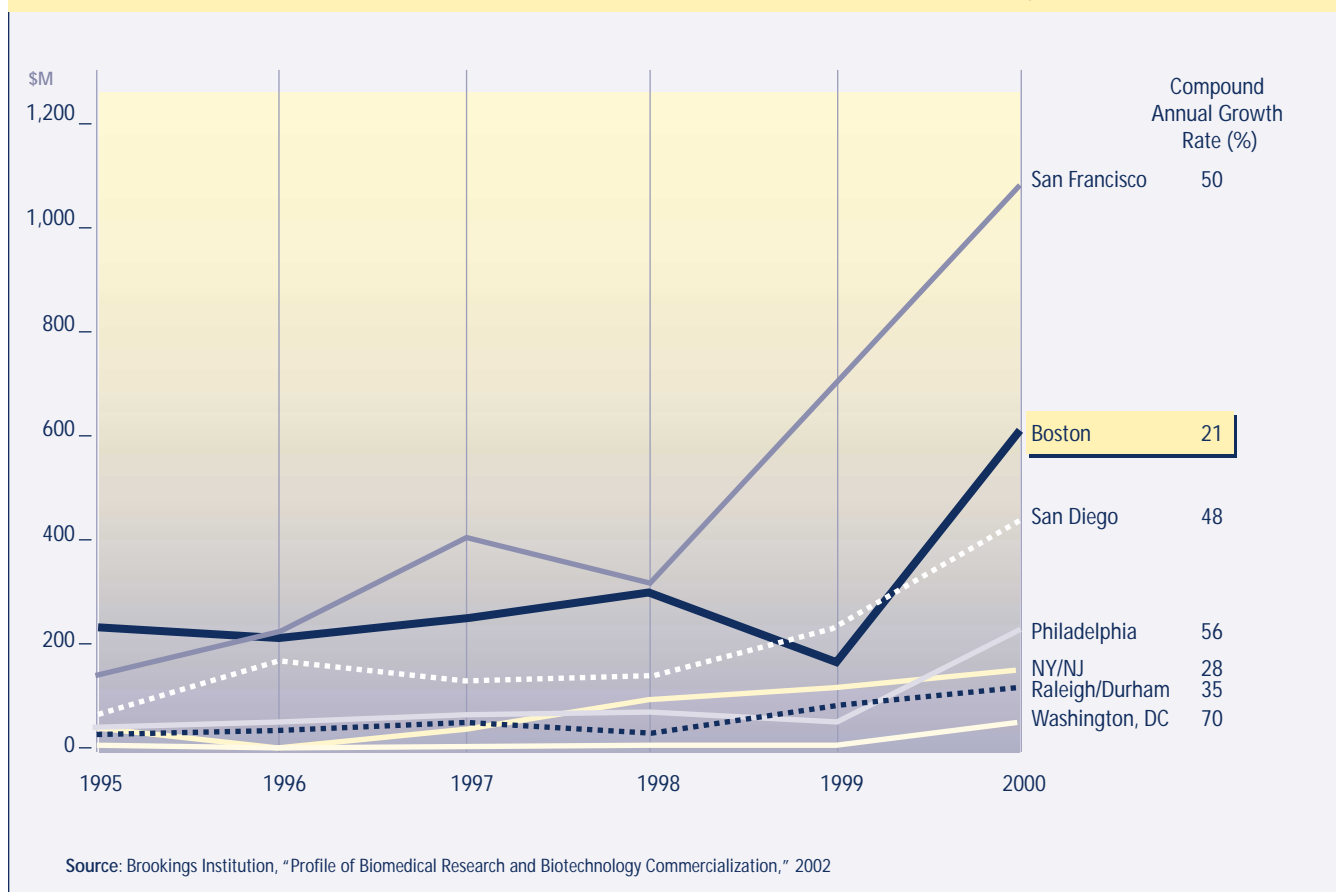
For example, a number of rival clusters have received consistent strong support from their state governments. In effect, state economic-development policy has served as a catalyst for the local biotechnology industry and as a facilitator for the organization of the life-sciences cluster as a whole. Although the pattern differs from state to state, all such efforts share some common characteristics:

- A clear recognition on the part of state government that biotechnology is central to the state's economic development, and an understanding that state government has a fundamental role to play;
- High-powered coordinating bodies that include key public officials and industry leaders to facilitate collaboration and networking—within the industry and among the industry, local academic institutions, and state agencies.
- Consistent support of life-sciences research, both through funding and through the development of enabling regulations such as the California legislature's recently passed law governing stem-cell research (see the sidebar "California: Working to Preserve Global Leadership" on p. 26);
- Aggressive courting of biotech companies to locate or expand in-state and, in some cases, the creation of state-funded institutions such as the North Carolina Biotechnology Center to spearhead this effort (see the sidebar "North Carolina: Aiming for the Top" on p. 28).
- State funding of new biotech startups via state pension funds or other sources of state-controlled money. For example, CalPERS, the California state pension fund, dedicates \$500 million to invest in biotechnology through the local venture capital community.

⁸We are borrowing the term—and the concept—from Annalee Saxenian, *Regional Advantage: Culture and Competition in Silicon Valley and Route 128* (Harvard University Press, 1994).

So far, Massachusetts has not taken so coordinated an approach to biotech economic development. For example, currently there is no single point of contact in state government to help companies navigate the complex regulatory environment. In a typical comment, one industry executive said, “We don’t know whom to contact; the system is totally opaque.” The state has also done relatively little to solicit biotech companies or help them locate their facilities in the state. And there are a number of outdated and redundant regulations in place that inhibit industry growth. As the competition for biotech development and jobs gets tougher, Massachusetts cannot afford to ignore the race for regional advantage (for a comparison of the state’s strengths and weaknesses with those of key rivals, see Exhibit 10 on p. 27). The state must develop a plan to attract and retain companies both when they are formed and when they make key growth decisions.

EXHIBIT 9: BIOPHARMACEUTICAL VENTURE CAPITAL FUNDING BY REGIONAL CLUSTER, 1995-2000



Although the Boston area has attracted the second-largest amount of biopharmaceutical venture capital funding in the country, investment is growing faster in competing regions.

California: Working to Preserve Global Leadership

FOR AN EXAMPLE OF HOW THE RACE FOR REGIONAL ADVANTAGE WORKS, CONSIDER THE CASE OF MASSACHUSETTS'S CHIEF REGIONAL COMPETITOR: CALIFORNIA.

The state is widely recognized as a global leader in biotechnology, with companies spread across the state and with particularly strong concentrations in the San Francisco Bay Area and in San Diego. State government has actively supported the industry's growth and development through legislative and fiscal policies designed to strengthen both industry companies and state-funded academic institutions.

California's three most recent governors—Republicans and Democrats alike—have taken actions that reflect their understanding of biotechnology's importance to the state's economy and that demonstrate the state's commitment to maintain its position as a global leader. In 1985, for example, Governor George Deukemejian established the Interagency Task Force on Biotechnology to develop consistent, streamlined regulatory processes and to promote the industry's growth. Chaired by the state secretary of trade and commerce, the task force is a cross-functional group composed of representatives from all state agencies with jurisdiction over biotechnology. The group's responsibilities include assessing federal and state regulatory policies, coordinating state policy development, serving as a liaison between state and federal agencies on biotechnology-related issues, developing public education programs, and helping biotechnology companies understand regulatory policies.

Governor Pete Wilson built on this effort in 1994, when he established the Council on Biotechnology to provide advice on policies to encourage the growth of biotechnology in California. The council consists of sixteen CEOs from California biotechnology companies who meet quarterly with either the governor or the secretary of trade and commerce.

Most recently, Governor Gray Davis signed legislation allowing the use of state funds for stem-cell research. This law is intended to strengthen the attractiveness of California as a location for biotechnology and to stimulate industry growth by attracting private-sector investment and scientific talent.

California has also made a commitment to supporting life-sciences research within its university systems. For example, the UC Systemwide Biotechnology Research and Education Program provides training grants to support biotechnology research and promotes academic research accomplishments to the general public, industry, and government. The University of California at San Francisco (UCSF) is building a 43-acre satellite campus at Mission Bay that will be focused solely on bioscience research.

Both the state government and state-funded academic institutions actively collaborate with industry. In December 2000, the state government created the California Institutes for Science and Innovation, four multidisciplinary research centers run in partnership by the state, the University of California, and private industry. The California Institute for Bioengineering, Biotechnology, and Quantitative Biomedical Research has the largest component of biotechnology-related research, but the other centers will incorporate some aspects of biomedical research in their activities as well. The institutes are funded by a combination of public and private funds, with one dollar of state funding for every two dollars of industry funding.

The state-funded university systems are also actively undertaking collaborative partnerships with industry. For example, the California State University system sponsors a Joint Venture Applied Research Program with industry, in which the partners undertake jointly funded research and research-training programs. This program benefits both parties by increasing university research funding and enhancing the technical expertise and research capacity of industry companies. The University of California system also has several collaborative partnerships with industry, including the BioSTAR program, in which industry companies provide matching funds for research activities with both parties sharing in the project's results. UCSF has established the Center for BioEntrepreneurship, which educates academicians on entrepreneurship and business-related topics. UCSF also offers courses on intellectual property for life scientists and creates opportunities for researchers and industry representatives to network.

EXHIBIT 10: THE RELATIVE ADVANTAGE OF THREE LIFE-SCIENCES CLUSTERS

	MASSACHUSETTS	CALIFORNIA	NORTH CAROLINA
Tax policy	<ul style="list-style-type: none"> • 10% R&D tax credit • 3% credit on depreciable assets • Single sales factor 	<ul style="list-style-type: none"> • 15% (in-house) and 24% (outsourced) R&D tax credits • 100% net operating loss carryforward • 7% job-creation tax credit • 6% manufacturing credit 	<ul style="list-style-type: none"> • 5% R&D tax credit • 7% tax credit for machine and equipment leases
State support for innovation	<ul style="list-style-type: none"> • Massachusetts Biomedical Initiatives (MBI) 	<ul style="list-style-type: none"> • State collaboration with industry and state universities to develop jointly funded research programs 	<ul style="list-style-type: none"> • State-funded North Carolina Center for Biotechnology (NCBC)
State-funded seed capital	<ul style="list-style-type: none"> • \$8 million cumulative MBI investment • Some state pension fund investment 	<ul style="list-style-type: none"> • \$500 million CalPERS Biotechnology Program 	<ul style="list-style-type: none"> • \$10 million North Carolina Bioscience Investment Fund (\$40 million cumulative investment over time) • \$42 million-\$150 million in tobacco-settlement money for biomanufacturing
Cost of doing business ¹	<ul style="list-style-type: none"> • Boston = 119.1 	<ul style="list-style-type: none"> • San Francisco Bay Area = 136.4 • San Diego = 105.5 	<ul style="list-style-type: none"> • Research Triangle Park = 97.0
Univ. patents (2000) ²	<ul style="list-style-type: none"> • 314 	<ul style="list-style-type: none"> • 548 	<ul style="list-style-type: none"> • 142
Life-sciences Ph.D.s granted (1999)	<ul style="list-style-type: none"> • Boston: 355 	<ul style="list-style-type: none"> • San Francisco Bay Area: 215 • San Diego: 82 	<ul style="list-style-type: none"> • Research Triangle Park: 166
Life scientists employed (1999)	<ul style="list-style-type: none"> • Boston: 4,980 	<ul style="list-style-type: none"> • San Francisco Bay Area: 3,090 • San Diego: 910 	<ul style="list-style-type: none"> • Research Triangle Park: 1,430
Relative advantage	¹ U.S. average index = 100 ² All high tech patents (including but not limited to biotech) Source: Battelle Memorial Institute; industry interviews; California Healthcare Institute; North Carolina Biotechnology Center; Brookings Institution "Profile of Biomedical Research and Biotechnology Commercialization," 2002; <i>Chronicle of Higher Education</i> ; KPMG, "Comparing Business Costs in North America, Europe, and Japan," January 2002; BIO; Massachusetts Biomedical Initiatives; BCG and Massachusetts Biotechnology Council analysis		

The Massachusetts life-sciences cluster has major strengths, but competing states are better organized to support biotech economic development.

North Carolina: Aiming for the Top

IN THE LATE 1970S AND EARLY 1980S, NORTH CAROLINA MADE A CONSCIOUS DECISION TO POSITION ITSELF AS A LEADER IN THE EMERGING BIOTECHNOLOGY INDUSTRY.

The state successfully developed a core strength in manufacturing and a substantial presence in research and development. Today, North Carolina is trying to build on its past successes in order to become a leader across all stages of the value chain—a one-stop shop for biotech companies.

In 1981, the state established and funded the North Carolina Biotechnology Center (NCBC) to develop a coordinated strategy to stimulate the growth of biotechnology in the state. With a staff of 53, the NCBC's mission is "to provide long-term economic benefit to North Carolina through support of biotechnology research, development and commercialization statewide."⁹ The NCBC's goals include establishing North Carolina as a leader in biotechnology, promoting the state's industrial development, strengthening research capabilities within both academic institutions and industry, developing partnerships across constituencies, and informing and educating the public about biotechnology. The NCBC strives to achieve these goals by expanding the number of companies in North Carolina, promoting collaboration across segments, and providing funding to targeted segments and programs.

North Carolina's comprehensive biotechnology strategy is developed and implemented by the state-funded NCBC. The NCBC aggressively recruits companies by promoting the area's strengths through outreach and marketing campaigns. Brochures with headlines such as "Trees, Tees, and Ph.D.s" highlight the state's attractiveness as both a place to live and a place to do business.¹⁰ The NCBC also builds relationships with companies, both domestically and internationally, to lure them to the state. For companies considering building in North Carolina, the NCBC provides a point of contact and works to facilitate processes such as site selection and permitting. The state's biotechnology strategy has clear, active state and local government support. Public officials prominently support the industry by attending key events and site openings, as well as by interacting with company management.

North Carolina ensures cross-fertilization of ideas and expertise by promoting collaboration among state entities, companies, and academic institutions. The NCBC works with companies and universities to provide programs such as networking events, grants to support collaborative industry-university research, matching programs to pair small and large companies for collaborative research, and funding for biotechnology-related conferences. The NCBC also teams with educational institutions to offer training programs in community colleges, teacher-training programs for K-12 and university-level courses, and educational grants for work force development programs and the K-12 biotechnology curriculum.

Targeted state-sponsored funding has been a key success factor in North Carolina's growth to date. The state's cumulative investment in biotechnology initiatives is \$135 million. This investment has triggered more than \$2 billion in direct out-of-state investment through venture capital financing, manufacturing investment, and federal research grants. State financial support has included funding for the NCBC's activities, a \$10 million investment in the NCBC Bioscience Investment Fund to provide seed capital, and grants to educational institutions. In addition, the Golden LEAF, Inc. foundation, which is responsible for investing the state's tobacco-settlement money, has committed \$42 million to expand biomanufacturing, with potential for an additional \$108 million over the next six years.

Despite its strength in manufacturing, North Carolina currently lags Massachusetts and California on several key industry metrics, such as NIH funding, number of Ph.D.s granted, and number of life scientists in the work force. Executing a clearly defined strategy to expand the state's biotechnology industry, to promote collaboration among different constituencies, and to provide strategic financial support, however, has created a strong base for future growth. Looking forward, this same combination could enable North Carolina to continue to capture an increasing share of the global biotechnology market, leveraging its current strength in manufacturing to become a leader across the biotechnology value chain.

⁹"North Carolina Biotechnology Center: Moving Biotechnology From the Mind to the Marketplace," North Carolina Biotechnology Center, July 2002.

¹⁰North Carolina Biotechnology Center pamphlet.

MAINTAINING WORLD-CLASS RESEARCH AND INNOVATION

World-class research has always been Massachusetts's core competitive advantage in biotechnology, and it will continue to be so. The state's universities, academic medical centers, and existing biotech companies constitute a remarkable engine of innovation that is both a spawning ground for new companies and a magnet for private biotech investment. One of the key future challenges for Massachusetts will be to maintain the innovativeness and productivity of its life-sciences research base.

Massachusetts universities grant approximately 350 life-sciences Ph.D.s every year (see Exhibit 11 on p. 30). Along with the state's top-ranked academic medical centers, they attract researchers from around the world. Roughly 5,000 life scientists are employed in the state—to our knowledge the largest per-capita concentration anywhere in the world. Massachusetts universities and medical centers also attract a substantial share of federal research funding. And in 2000, they received 314 high tech patents.

It is impossible to overestimate the importance of this research base to the Massachusetts biotech industry. When we asked biotech executives why they chose to locate in the state, the top reasons were "proximity to universities" and "access to research scientists." As one told us, "We started here because our founders come from Massachusetts universities; we stay here because the best people are here."

Massachusetts cannot take this advantage for granted. Despite extraordinary strength, there are some emerging signs of potential weakness. As the race for regional advantage intensifies, competition for federal research funding is also becoming tougher. And the recent California legislation that allows state funds to be used for stem-cell research has raised concerns in the Massachusetts life-sciences community that the state's leadership may be hindered by the absence of a clear framework for pursuing controversial cutting-edge research. "We're very concerned about restrictions," said one leading researcher. "We're worried that we may not be able to use the best technologies to conduct innovative research."

Even more serious are the signs that Massachusetts is not converting its rich research base into commercial opportunities at the same rate as some of its rivals. Take the example of the new field of bioinformatics, which uses computational approaches to analyze biological data. Although there are differences of opinion within the industry about just how important bioinformatics will be, many researchers believe it represents a fundamentally new way of doing biopharmaceutical research. The fact is, Massachusetts has largely missed the bioinformatics revolution—at least in terms of being the home of many bioinformatics start-ups. California already has 16 public companies devoted to bioinformatics. Massachusetts is yet to have one.¹¹

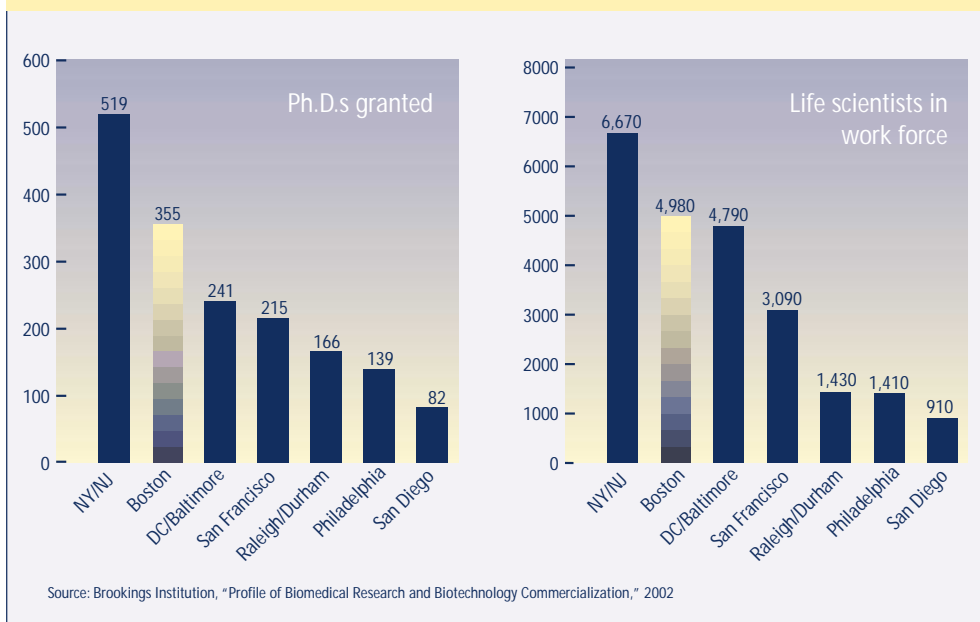


World-class research has always been Massachusetts's core competitive advantage. The state cannot take this advantage for granted.

¹¹ See "Financial Snapshot," *Signal Magazine*, August 2002.

With the exception of the New York-New Jersey metropolitan area, Boston educates and employs more life scientists than any region in the country.

EXHIBIT 11: LIFE-SCIENCES GRADUATES AND EMPLOYEES BY REGION, 1999



Despite its admirable success at developing new drugs, the Massachusetts biotechnology industry has also yet to produce a true “blockbuster” product (i.e., producing more than \$1 billion in annual revenues). The absence of a local blockbuster has implications for commercial research. California-based Amgen, for example, had combined revenues of \$3 billion in 2000 from sales of its two blockbusters Epogen and Neupogen, which has fueled enormous growth in the company’s commercial research investment. Massachusetts research has yet to be able to take advantage of a similar local funding engine.

Finally, the Massachusetts portfolio of companies is at a delicate transition point. Companies that have been largely dedicated to research and discovery are moving into more expensive development and manufacturing precisely when the IPO market and financial markets in general are extremely weak. Only 3 out of the 38 Massachusetts public companies with products in the clinical-development pipeline have a positive cash flow. And 29 companies, accounting for a full third of the local pipeline, will need fresh capital within the next two years (see the sidebar: “Massachusetts ‘Teenage’ Biotechs: High Potential, Big Vulnerabilities” on p. 21). Many of the state’s key biotech companies could lose their independence if their needs for increasing financing cannot be met by the capital markets. Such a scenario could have a major impact on the local commercial research base.

In the years ahead, it is essential for Massachusetts to retain and strengthen its position with respect to research funding dollars, fair and supportive regulation that provides a framework for innovation, the breadth of life sciences research capability across multiple universities, and the rate of new company formation. The goal: to continue to increase our share of the world’s biotechnology research pipeline.

MOVING DOWN THE DRUG-DEVELOPMENT VALUE CHAIN

The drug-development value chain can be divided into four basic steps: research, in which promising compounds to treat a particular disease are identified; development, where the compound is refined and tested in clinical trials in animals and humans; manufacturing, where the compound is produced in large quantities; and commercial, including activities such as sales and marketing (see Exhibit 12).

Unlike the case of research, Massachusetts has not been a major center for downstream functions such as development and manufacturing. Only about 10 percent of the state's biotech companies are currently involved in manufacturing. Of those, more than half do their manufacturing outside the state. Given the richness of the current pipeline, more and more Massachusetts biotech companies will be moving down the value chain in the years to come. Early indications, however, are that they may choose to pursue these downstream activities elsewhere.

Evidence suggests that the further a biotech company moves down the value chain, the less likely it is to locate activities in Massachusetts (see Exhibit 13 on p. 33). For example, quite a few companies do initial development and pilot manufacturing in-state because of the value of co-location with research facilities. Remarkably few, however, conduct their clinical trials in-state, despite the presence of accomplished clinical investigators at our leading research hospitals (although Massachusetts



Only about 10 percent of the state's biotech companies are currently involved in manufacturing.

EXHIBIT 12: THE DRUG-DEVELOPMENT VALUE CHAIN



Drug development is a complex process taking up to 15 years and costing roughly \$800 million.

Making It in Massachusetts: The Wyeth Story

FEW PEOPLE REALIZE THAT MASSACHUSETTS IS HOME TO ONE OF THE LARGEST BIOPHARMACEUTICAL MANUFACTURING FACILITIES IN THE UNITED STATES.

In 1996, Wyeth (formerly American Home Products Corporation) acquired Genetics Institute, a biotechnology pioneer founded by two Harvard University scientists. Since then, Wyeth has expanded the original Genetics Institute manufacturing site, located in Andover, into a seven-building, 65-acre campus that includes 300,000 square feet of laboratory space and 365,000 square feet of manufacturing space. The site employs nearly 2,000 people in a broad range of development, manufacturing, quality control, and administrative jobs. Many of these employees have been trained by Wyeth directly, or by local schools that have partnered with the company in designing training programs.

The expansion of the Andover campus serves as a testimony to Wyeth's commitment in making Andover one of its key centers of excellence for biopharmaceutical manufacturing. But it also illustrates the critical role state government can play in facilitating economic development in the life sciences. The positive contributions made by public authorities and agencies include:

- Coordination through the Massachusetts Office of Business Development in accelerating permitting reviews;
- Guidance from the secretary of economic affairs and the secretary of environmental affairs in meeting state regulations for assessing the environmental impact of the site expansion;
- Commitment from the Massachusetts Highway Department to accelerate improvements to the I-93/Rte 125 interchange and adding traffic signals at a key intersection near the site;
- Grant awards from Public Works Economic Development funds to the town of Andover to provide additional access to the area;
- Assistance from the Office of Business Development and the Highway Department to respond to litigation brought by a small group of local residents that could have halted the expansion; and

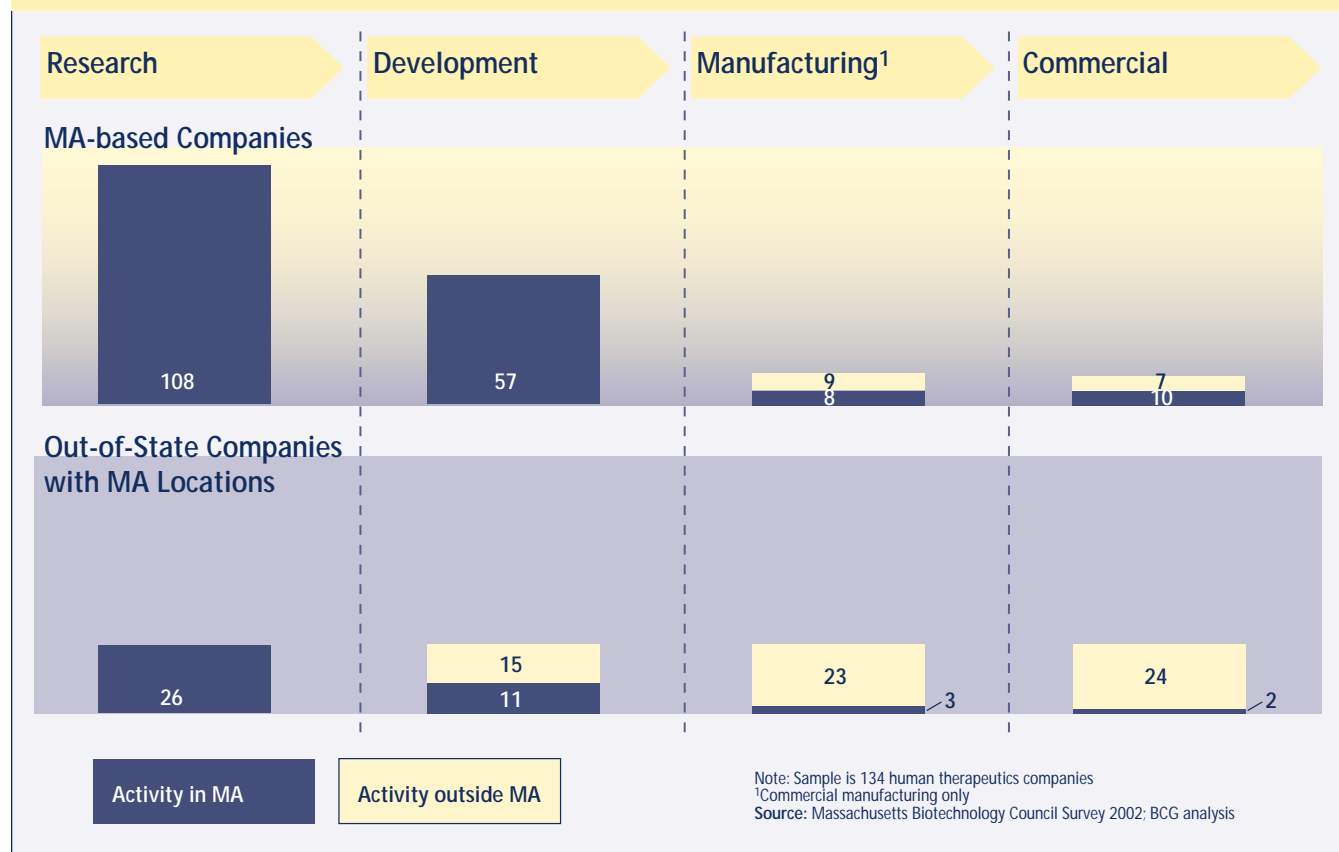
- State support for employee training through the Building Essential Skills through Training (BEST) program.

The state's role in accelerating the regulatory process, improving the physical infrastructure, and developing human capital helped Wyeth's management team make the case for developing the Andover campus into a major location in its global biopharmaceutical business.

The local community also played a key role in making Wyeth's Andover campus possible. Wyeth and the town of Andover have worked closely to develop and maintain a mutually supportive relationship. For example, Wyeth has worked with local schools to educate students about careers in science. The company has given presentations at schools and invited students to visit and observe working laboratories in an effort to increase interest in the sciences. It has also developed an innovative annual before-school program that introduces children to science and its impact on their everyday lives. And at the college-level, Wyeth has created a summer internship program that every year brings nearly 100 students to its Andover site and to its discovery research laboratories in Cambridge.

Members of the local Wyeth management team sit on several boards of directors in Massachusetts, and the company has been involved in creating biotechnology training programs in the state. The Andover site has also been recognized for its leadership in transportation demand management by the U.S. Environmental Protection Agency. In May 2002, EPA administrator Christine Todd Whitman visited the site to recognize the company as a national leader in the EPA's Commuter Choice Leadership Initiative.

EXHIBIT 13: ACTIVITIES LOCATED IN MASSACHUSETTS BY STAGE OF VALUE CHAIN



companies rank second, after California, in developing products requiring clinical trials, Massachusetts hospitals lag several other states in the number of clinical trials performed). And very few do manufacturing in Massachusetts. The older a company gets, the smaller the share of its jobs that are located in Massachusetts. In the first five years of its existence, a Massachusetts biotech company locates 80 percent of its jobs in the state, on average. By the time a company is more than 16 years old, however, that share has declined to 50 percent.

From the perspective of state economic development, this is an extremely worrisome trend. As activities move down the value chain, a much wider range of job opportunities becomes available—for example, positions as lab technicians or in manufacturing or quality control and assurance. Such jobs spread the benefits of biotech employment to a far broader range of the population.

What's more, downstream jobs, especially in manufacturing, tend to be highly stable geographically. The FDA's lengthy and complex drug-approval process includes approval of the manufacturing process and site. Thus once a manufacturing site wins federal approval, it is not likely to be moved. Even if a local company is acquired by an out-of-state investor (a plausible scenario for at least some Massachusetts companies, given the high degree of merger-and-acquisition activity in the biopharmaceutical sector), the manufacturing facility is likely to stay in Massachusetts. This will also anchor in the state related activities such as development because of the synergies associated with co-location. (For an example, see the sidebar "Making It in Massachusetts: The Wyeth Story.")

An analysis of 134 human-therapeutics companies (either based in Massachusetts or with facilities here) demonstrates that the farther one goes down the value chain from research, the less likely companies are to locate activity in the state.



Over the next three years, the biotech companies founded in the early nineties will decide where to locate their manufacturing facilities. If Massachusetts does not fight for these jobs, it will be an enormous missed opportunity.

What explains Massachusetts's reputation as an unfriendly environment for downstream activities like manufacturing? Interestingly, it is not the state's relatively high wages and cost of living. The biotech executives we interviewed consistently said that labor costs were not the major factor in the decision to pursue development and manufacturing activities outside of Massachusetts.

All else being equal, many companies would prefer to locate their downstream facilities in Massachusetts. In the early stages of development, such as bioprocessing and pharmaceutical R&D, proximity to research scientists is key. And for certain types of manufacturing—pilot manufacturing, large-molecule manufacturing, complex R&D-intensive manufacturing techniques, and even packaging and finishing—there is a great advantage in locating close to development centers and headquarters. "There is a very delicate passing of the baton," one executive explained. "The n^{th} plant can be in Ireland, but for the first one, the instinct is to go with Cambridge. We'd pay a 20 percent premium to stay here."

The key issue, according to the biotech executives we interviewed, is the perceived unpredictability of the local regulatory and permitting environment. Companies making a cost-benefit decision on siting a plant will look at two dimensions of cost: opportunity cost and direct cost. Since creating a manufacturing facility is a major investment, companies typically try to delay the decision until the last possible moment, usually after the drug in question has received regulatory approval. Once a company decides to move forward, it is absolutely essential to ready the new facility as quickly as possible, since a delay in manufacturing is a delay in time-to-market. In this respect, the opportunity cost of delay is the dominant component of cost. Executives cited zoning and permitting delays, legal holdups at the city level, and lack of standardized approval processes as major opportunity costs. As one said, "In Massachusetts, you never know what problem you'll run into."

And yet, in the past, Massachusetts government has shown that it can mobilize to win biotech manufacturing jobs for Massachusetts. The classic example is Genzyme's 1991 decision to build its manufacturing plant at Allston Landing in Boston. Initially, the company was considering out-of-state locations. But rapid action on the part of then-Governor Weld and the Boston Redevelopment Authority persuaded Genzyme CEO Henri Termeer to locate the facility in Boston. Both the state and the City of Boston worked with Genzyme to identify and evaluate potential sites. Once the Allston location was chosen, each assigned an individual to work with Genzyme to expedite the permitting process. The collaborative effort was so successful that the company broke ground in April 1992, only four months after selecting the Allston site.

What Massachusetts needs is to institutionalize the responsiveness and coordination illustrated by the Genzyme story. Over the next three years, the great bulk of biotechnology companies founded in the early nineties will be decide where to locate their manufacturing facilities. If Massachusetts does not fight for these jobs, it will be an enormous missed opportunity.

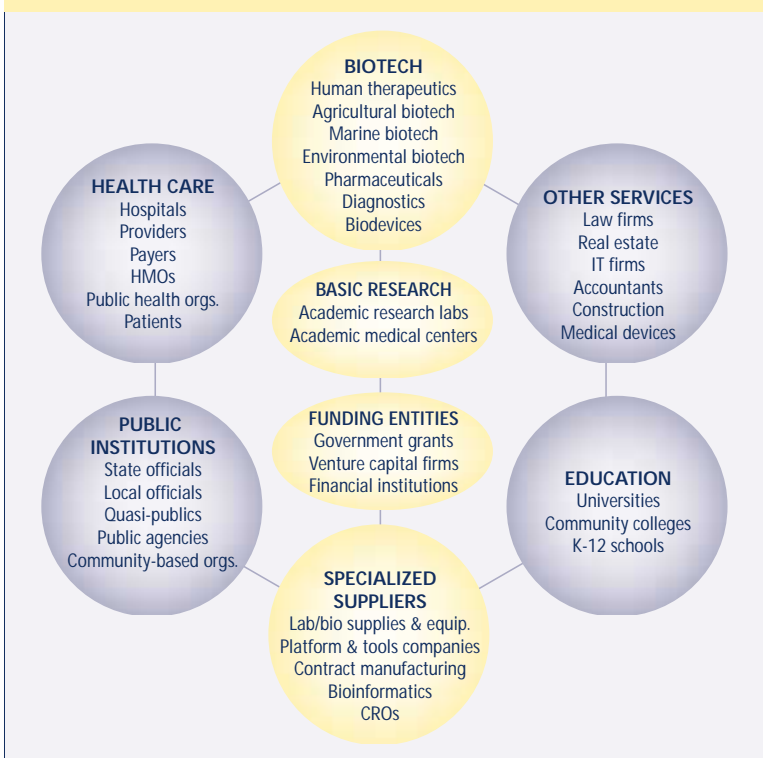
LEVERAGING THE LIFE-SCIENCES ECONOMIC CLUSTER

Biotechnology is an integral part of a far broader life-sciences economic cluster.¹² Boundaries are blurring between previously distinct industries such as biotech and pharmaceuticals and between product segments such as therapeutics, diagnostics, and devices. Nonprofit universities and academic medical centers and for-profit life-sciences businesses are becoming more and more interdependent. Life-science venture capital firms are playing an increasingly dynamic role across the entire cluster. And many auxiliary businesses ranging from biotech equipment suppliers to organizers of clinical trials to life-science accounting and law firms all contribute to and depend upon the economic health of the sector (see Exhibit 14).

Taken as a whole, the Massachusetts life-sciences cluster is responsible for roughly 13 percent of the state's employment and generates some \$16.2 billion in wages.¹³ The different types of institutions in the cluster are interconnected through alliances, financing relationships, and a flow of goods, information, and personnel. And they often have shared interests and common issues. But perhaps most important, regional competition is increasingly taking place at the level of the cluster as a whole.

There is a considerable academic literature on the dynamics of regional industrial networks.¹⁴ A prominent theme is how in dynamic technical fields such as biotechnology, the intensity of collaboration among industry companies and between companies and academic institutions is an essential contributor to the cross-fertilization that drives research innovation and creativity. Such collaboration helps different cluster players remain current on the industry's rapidly evolving technical aspects and move faster in a competitive arena that rewards innovation and speed-to-market.

EXHIBIT 14: THE LIFE-SCIENCES ECONOMIC CLUSTER



¹²Michael Porter defines clusters as "geographic concentrations of interconnected companies, specialized suppliers, service providers, firms in related industries, and associated institutions (for example, universities, standards agencies, and trade associations) in particular fields that compete but also cooperate." See Michael E. Porter, "Clusters and Competition: New Agendas for Companies, Governments, and Institutions," in *On Competition* (Harvard Business School Press, 1998), pp. 197-287.

¹³See "The Massachusetts Health-Care Industry: A Stalled Engine of Economic Growth," prepared for the Massachusetts Hospital Association by Standard & Poor's DRI, April 2000.

¹⁴See, for example, Saxenian, *Regional Advantage*; Michael E. Porter, "Clusters and Competition;" and Michael E. Porter, "Clusters and the New Economics of Competition," *Harvard Business Review*, November-December 1998, pp. 77-90.

Lessons from Route 128

MASSACHUSETTS HAS BEEN ENGAGED IN A BATTLE FOR REGIONAL ADVANTAGE BEFORE.

In the 1960s and '70s, the state developed a thriving high technology industry along Route 128. Some of the world's most admired technology companies—Digital Equipment, Wang, Data General, and Apollo—were founded in Massachusetts. By 1990, however, the situation had changed dramatically. Route 128 had been largely eclipsed by California's Silicon Valley as a global center of the computer industry. Many Massachusetts companies had shut down, gone bankrupt, or been acquired. Today, the flagship companies of the industry are largely based in Silicon Valley.

What went wrong? The most detailed analysis of the Massachusetts industry's decline suggests that the problem lay in the culture and industrial organization of Massachusetts companies.¹⁵ Route 128 companies were typically organized as traditional large vertically integrated companies. They had highly stable work forces and relatively strong boundaries between the company and the outside world. Intellectual property was treated as proprietary. There were relatively few alliances or partnerships with other firms.

Silicon Valley, by contrast, had a much more open and networked style of industrial organization. Companies were small and entrepreneurial. Employees constantly moved from one company to another in search of a better position. Knowledge and information often moved with them, supplemented by the rich cross-company social and professional networks in the Valley. The result was a far more fluid and innovative industrial culture and organization, one that encouraged innovation and flexibility and helped Valley companies adapt more quickly to changes in the industry.

The networked organizational culture best suited to the computer industry is equally suited to biotechnology. The question remains: can the Massachusetts life-sciences cluster embrace the collaborative networked style in a way that its colleagues in the computer industry could not? Or is there something systemic in the culture and organization of Massachusetts institutions that inhibits the conversion of research richness into commercial power?

¹⁵See Saxenian, *Regional Advantage*.

One study of the biotechnology industry, for example, suggests that the number of network ties that a biotech firm or institution has within a cluster, as well as its position and centrality in relation to other firms in the cluster, can affect performance.¹⁶ Those firms or institutions that successfully develop collaborative relationships are more likely to have access to information, financial resources, and alliance opportunities.

Increasing the number of these network relationships increases the number of available opportunities, as well as their potential impact and payoff. In addition, external network R&D connections generally have a synergistic effect on the benefits from internal R&D efforts. "In the short term," the authors write, "firms lacking in alliances will be slower to generate research discoveries, obtain patents, and turn scientific results into marketable products. In the long run, firms that learn to manage diverse portfolios of collaboration, involving multiple projects at different stages of development, are less likely to fail."¹⁷

¹⁶Walter W. Powell et al., "Network Position and Firm Performance: Organizational Returns to Collaboration in the Biotechnology Industry," in Steven Andrews and David Knoke (eds.), *Networks In and Around Organizations*, a special volume in the series *Research in the Sociology of Organizations*. (Greenwich: JAI Press, 1999).

¹⁷Powell et al., "Network Position and Firm Performance."

Traditionally, the Massachusetts biotechnology industry has been highly collaborative, with excellent relations between firms and academic institutions. But as the life-sciences cluster has become larger and more complex, with many different organizations and cultures taking root, it is less clear that sufficient mechanisms are in place to capture the value of the network for commercial success.

For example, our interviews disclosed substantially less connectivity than one might expect between home-grown biotech companies and the recent crop of pharmaceutical firms that have located in the state. Many researchers we interviewed in the academic community argued that there are substantial additional opportunities for idea exchange, technology transfer, and other efficiencies—if only they could find ways to work more closely both with other universities and with commercial partners. Still others felt that the Massachusetts cluster needs to be more open to ideas and technologies from outside the region. “This is a more insular environment than we imagined,” one scientist from a pharma research center that had moved into the state told us. “It’s not as open as we thought.”

Many biotechnology executives we interviewed singled out a specific missed opportunity for collaboration: the problems they have in conducting clinical trials in-state. The executives said that doing trials in Massachusetts hospitals is too costly and too slow. “It’s incredibly difficult to work with the hospitals here for clinical trials,” said one. “I’d like to but it is just so difficult.”

We were left with the impression that the life-sciences cluster has reached a stage in its evolution where its size and complexity have outgrown the traditional mechanisms for interaction. The cluster has relatively little formal organization and few permanent clusterwide institutions, and this makes it difficult to take advantage of potential synergies and address common issues. To some degree, the cluster is a victim of its own success. The very strength of its dominant institutions sometimes makes it difficult for those institutions to work together (see the sidebar “Lessons from Route 128”).

The experience of some of Massachusetts’s rivals suggests that state government can play an important role in leveraging the strengths of the life-sciences cluster. But it is also time for the cluster to start organizing itself, and for its leadership to start charting a strategic course for the cluster as a whole. In the concluding sections of the report, we address what state government and the life-sciences community can do to address the challenges facing the biotechnology industry and the life-sciences cluster.



The Massachusetts life-sciences cluster is responsible for roughly 13 percent of the state’s employment and generates some \$16.2 billion in wages.

THE ROLE OF STATE GOVERNMENT



Massachusetts has a unique opportunity to create a new pillar for the state economy. To seize that opportunity, state government needs to send a strong signal to all the players.

As the biotech industry matures and the stakes in terms of wealth creation increase, Massachusetts needs to compete at a different level. Massachusetts has a unique opportunity to create a new pillar for the state economy. To seize that opportunity, state government needs to send a strong signal to all players—both those already present in the state and those waiting on the sidelines.

The recommendations in this chapter are the product of our work with nine topic teams established by the MBC for this report. Each team consisted of four to six topic experts representing a wide range of organizations from the life-sciences cluster. In a highly detailed participatory process, the experts identified roughly 100 specific policy initiatives to make Massachusetts a better place to conduct biotech activities (for the complete list of topic teams and initiatives, see Appendix I, starting on p. 49). Their recommendations fell into four broad categories.

1. Become a champion of and catalyst for biotech economic development. Active state leadership is the most important condition for Massachusetts to compete successfully against other clusters. With the exception of California, none of these regional competitors has the natural assets that Massachusetts has for fostering a vibrant biotechnology sector. State leadership and well-executed strategies, however, have allowed other biotech regions to attract investment, companies, and jobs. Of the Massachusetts companies that have located operations out of state, few go because other places are intrinsically superior. Rather, they go because they feel more welcome elsewhere than in their own home state.

1a. Create the right leadership team. Becoming a champion of biotech economic development means identifying the life-sciences cluster as a key engine for growth and wealth creation, defining a clear strategy to make the most of the opportunities associated with the cluster, and communicating broadly to exert a positive influence on all stakeholders. This will require the personal involvement of the governor and the appointment of biotech champions at multiple levels of the administration. We recommend the creation of the following four roles:

- A secretary of economic affairs with the mandate and the resources to capture the opportunities in the life sciences;
- A senior advisor for science and technology, reporting directly to the governor;
- An advisory board made up of industry representatives to coordinate and strengthen the life-sciences education agenda; and
- A full-time point person for the industry in the Massachusetts Office of Business Development.

1b. Champion Massachusetts biotech at the federal level. State officials need to make sure that the interests of Massachusetts are well served by federal legislation and regulation. The office of the governor should stay in close contact with federal agencies such as the FDA and National Institutes of Health (NIH) that fund and regulate life-sciences activities and strive to maintain the success of Massachusetts-based institutions and companies in attracting significant research dollars to the state. When in Washington, Massachusetts leaders should be ambassadors for the important economic sectors of the state, and the life-sciences cluster should be one of their top priorities.

1c. Facilitate collaboration in the life-sciences cluster. As a champion of the life sciences, the state should also encourage greater cooperation within the life-sciences economic cluster. By serving as a facilitator of public-private partnerships, the state can send a strong message to the community and unlock some of the untapped potential of the cluster. Potential areas of collaboration include developing new financial and pricing models in health care to support the development of innovative therapies, or creating a consortium of companies and academic institutions to address the urgent area of biodefense.

1d. Build public support. Massachusetts can be a biotechnology leader in the long run only if the citizens of the state share this vision. To make this happen, the state and the industry will need to undertake a program of education and reassurance. An outreach program should stress the soundness of the regulatory environment and the benefits of having a clean, low-impact industry that provides high-skilled jobs in the state. Building support also implies that patients in Massachusetts have access to high-quality innovative health care solutions when they need them. All citizens of the state should benefit from the hard work and significant investments made by their fellow citizens in offering cures that make a significant difference in patients' lives.

2. Improve the business climate. With financial markets largely closed to public offerings for the moment, private and not yet profitable public companies must reduce their burn rate if they want to survive through the current economic cycle. Though the industry recognizes that Massachusetts will never be a low-cost location for doing business, several initiatives could be undertaken to improve the attractiveness of the Massachusetts business climate.

2a. Develop a statewide life-sciences research and innovation framework. To be able to make multiyear investments in research, biotechnology companies need a clear and predictable regulatory system. That system needs to define an environment in which new research will be welcome and to define transparent rules by which science on the frontiers of knowledge can move forward.

The biotech industry recognizes the concerns of the public and believes that the state can work with the industry to provide leadership in the continued discussion of emerging issues, focusing on science-based regulation and risk management, multiagency working relationships, and stakeholder participation. Here are some of the key principles that ought to govern the creation of a statewide research and innovation framework for biotech organizations:



To be able to make multiyear investments in research, biotechnology companies need a clear and predictable regulatory system.



Discovery and innovation should be encouraged, despite the inevitable uncertainties they entail. All regulatory decisions should be driven by open debate and objective, scientific analysis of the evidence.

- Discovery and innovation should be encouraged, despite the inevitable uncertainties they entail. All regulatory decisions should be driven by open debate and objective, scientific analysis of the evidence.
- The mechanism of institutional review boards, used to monitor clinical trials, is an appropriate model for public discussion of industrywide issues where data are hard to find and scientific evidence is insufficient.
- The role of the FDA and the EPA in setting stringent guidelines should be recognized; local and state authorities should avoid adding layers of regulation on top of existing federal regulations.

2b. Streamline the regulatory environment. At every stage of the biotechnology value chain, time is of the essence. Unnecessary delays due to burdensome regulations can deter companies from operating in a particular location. State regulatory agencies should review and reevaluate existing regulations for appropriateness. And they should partner with the biotech community to build a system of performance-based regulation, along the lines of the Environmental Results Program developed by the Massachusetts Department of Environmental Protection.

2c. Stabilize the tax environment. The biotechnology industry recognizes that considerable progress has been made over the last decade in making Massachusetts more attractive for research-intensive companies. The single sales factor (used to calculate the corporate income tax base) and the research-and-development and investment tax credits provide effective incentives for companies to locate discovery, manufacturing, and headquarters operations in Massachusetts.

To reap the full benefits of these initiatives, however, the state needs to act on two fronts. First, to increase the predictability and stability of the tax environment, it should make those provisions permanent and resist any temptation to increase tax rates. Second, the state should consider key adjustments to the law to make sure that early stage start-ups and not yet profitable biotech companies can benefit from the tax credits.

One possible approach would be to create a market in R&D and investment tax credits. Such a market would allow companies that currently cannot take advantage of these credits (because they have no profits) to sell their credits to profitable companies that can use them. Another key change would be to revise the antiquated definition of an R&D corporation in Massachusetts law, which currently excludes companies without a revenue stream from the benefits of this designation.

3. Plan the physical infrastructure. The components of the state's physical infrastructure—roads, transportation systems, zoning, utilities, telecommunications, etc.—are an absolutely critical enabling factor in economic development. They must be designed with the needs of biotech economic development in mind. The state and its agencies have a crucial role to play in promoting a “smart growth” policy that reconciles quality of life and economic development. Because of its relatively low impact on the environment (i.e., low number of employees per square foot and strictly regulated, nonpolluting facilities), biotech can be the showcase industry for such a policy.

3a. Plan the smart growth of the cluster. Biotech development unfolds according to a distinctive economic logic. Although the geographic dispersion of the industry has increased in recent years, the value of co-location means that most further development will take place in relatively close proximity to existing facilities. State agencies need to take the current biotech geographical distribution into account. The state should create a joint public-private task force to identify and develop key locations that will meet the needs of the industry for complex manufacturing facilities and to make sure key transportation and communication links between existing centers and new development are in place.

3b. Partner with local communities. Although local communities have full jurisdiction over most zoning and permitting issues, the state government can work with those communities that want biotech development to help the communities and companies find each other. One way to do so would be to create, in cooperation with the industry, a framework for biotech development—a set of uniform zoning and permitting procedures and infrastructure standards—and then encourage towns and cities seeking development (and where biotechnology is an appropriate option) to “opt in” to the framework. Those communities that establish regulations, procedures, and infrastructure recommended by the framework could be showcased by state agencies with companies looking to locate or expand in Massachusetts.

3c. Capture the manufacturing opportunity. As state agencies and the industry work to create a systematic approach to infrastructure planning, they must also immediately make some tactical moves. Unfortunately, the current perception in the biotech community is that Massachusetts is an unattractive location for manufacturing. The state needs to move fast to rectify that impression. One immediate step would be to identify sites that already have the permitting in place and advertise these locations heavily to companies with products in clinical development. Once a company expresses interest in a particular location, the state should mobilize its agencies and work with the local authorities and the company to define what types of infrastructure should be put in place and by when. Having a full-time person in the Massachusetts Office of Business Development to pull together the resources of various programs, coordinate the different agencies, and be the interlocutor for the companies that are in the process of making these decisions is critical. The state should also consider establishing manufacturing centers of excellence and set up special enterprise zones for these activities.



Although local communities have full jurisdiction over most zoning and permitting issues, the state government can work with those that want biotech development to help communities and companies find each other.

BEST in BIOTECH: A Pilot Project for Training Biomanufacturing Technicians

THE NEED FOR SKILLED BIOMANUFACTURING TECHNICIANS HAS BEEN INCREASING GEOMETRICALLY, AS MANY BIOTECHNOLOGY COMPANIES COMPLETE CLINICAL TRIALS AND START PRODUCING NEW DRUGS COMMERCIALY.

A chronic shortage is quickly reaching crisis proportions at the front line of biomanufacturing in New England, where more than 1,000 new biomanufacturing jobs are anticipated in the next two years, while fewer than 100 students are in training. The lack of updated school facilities, as well as faculty familiar with cutting-edge bioprocessing techniques, has exacerbated the shortage.

One response is a pilot worker-training program known as BEST in BIOTECH, developed by the MBC and its foundation MassBioEd. BEST of BIOTECH was one of six programs awarded grants by the Building Essential Skills through Training (BEST) program, a broad initiative of the governor's office and Commonwealth Corporation, the Department of Labor and Workforce Development, the Department of Education's Division of Employment and Training, and the Department of Transitional Assistance. With the help of a \$500,000 state grant, the MBC, and MassBioEd have partnered with MBC-member companies, regional work force investment boards, and Roxbury and Middlesex Community Colleges to create an innovative \$1.6 million coinvestment program.

BEST in BIOTECH is reaching into urban communities to establish a pipeline of potential workers who will benefit from entry into a cutting-edge industry. It is implementing a hands-on, industry-driven curriculum, designing a screening test for

potential workers, and offering remedial programs in basic skills for those who do not pass the screening test. Finally, it screens and hires prospective students, then pays their tuition and salary during an intensive four-week training program.

BEST of BIOTECH is a brand-new program, and its effectiveness remains to be demonstrated. But the hope is that it will be a model for work force development in the biotech industry that can be reproduced at other community colleges around the state as the needs of the manufacturing sector develop in other key geographic regions.



4. Prepare the state's human capital. As in most research-intensive industries, one of the most critical assets in biotechnology and the life sciences as a whole is human capital. The final area for state-government activism is maintaining and improving the Massachusetts human skill base in three key ways.

4a. Continue to attract world-class research talent. The quality of scientific research and the breadth of innovative health care solutions from Massachusetts research institutions are unparalleled. This creates an inflow of research funds and scientific capital that leads to more discovery and reinforces a virtuous circle. The state has an important role to play at the federal level in preserving the current peer-review system for approving federal research funding and in making sure that excellence in research is the only criterion rewarded by federal agencies.

The role of international scientists who join the local community and play a key role in advancing research in public and private organizations is also well documented and recognized. Massachusetts should continue to pursue an open-door policy and use its influence over federal legislation and agencies to prevent unnecessary hurdles, delays, and restrictions related to immigration. “Since September 11, we have had grants and positions going unfilled, because visas are so difficult to get,” said the head of one university research lab. “We don’t want passport control between labs.”

Finally, one place where state government can directly influence the state’s capabilities for life-sciences research is in the state university system. For example, the state should consider properly funding and supporting the University of Massachusetts so it can be a strong center of life-sciences research and work force development much like the California state university system.

4b. Develop the state work force. As the biotechnology industry evolves from its traditional research focus to a broader set of activities such as development, manufacturing, and marketing, the state’s institutions of higher education will need to prepare the local work force for new employment opportunities. In particular, Massachusetts needs to develop education and training programs for the increasing broader array of technical jobs (from entry level to more advanced) to complement existing bachelor of science and Ph.D. programs. One example of the kind of public-private partnerships that can make a difference is the BEST in BIOTECH initiative, which involves employers with two state community colleges (see the sidebar “BEST in BIOTECH: A Pilot Project for Training Biomanufacturing Technicians”). Such joint programs should be expanded to keep up with the growth of the cluster.

4c. Improve science education in K-12. The life-sciences education agenda is a key platform for the next generation of Massachusetts human capital. In recent decades, exposure to science in general and to life sciences in particular has decreased, while at the same times advances and innovation have accelerated. The state should work to make life sciences an important part of the curriculum from kindergarten to twelfth grade. On the one hand, this will require making sure teachers have the tools and resources they need to teach basic science. On the other, it will require integrating the latest developments and technologies into the K-12 curriculum. We recommend the creation of an advisory board with industry representatives to define priorities for life-sciences education, identify synergies in the curriculum across the different education systems, appoint specific task forces, and ensure that initiatives are coordinated.

The above recommendations represent a comprehensive agenda. This agenda will be difficult to attack all at once and is likely to take many years to complete. But the most important thing for state government to do now is to demonstrate that it recognizes the importance of the broad agenda, and then to act on some subset of the key opportunities. Together with the biotech industry, it must work to create the right political and public-policy context for what will inevitably be a multiyear commitment.



The life-sciences education agenda is a key platform for the next generation of Massachusetts human capital.

THE ROLE OF THE MASSACHUSETTS LIFE-SCIENCES COMMUNITY



Realizing the power of the network will require dedication of time and energy to building relationships, infrastructure, and common organizations.

State government can play a significant role in developing a strategy to support life-sciences industries in Massachusetts. But state policies alone are not sufficient to ensure the continued growth of the Massachusetts life-sciences cluster. Cluster members themselves must take the lead in driving the cluster's development.

In particular, the Massachusetts life-sciences cluster must tighten the cohesiveness of its network and increase collaboration both within and across cluster segments. The goal should be to create a more integrated and more coordinated cluster and a collaborative environment that fosters cross-fertilization and innovation by Massachusetts companies and universities.

1. Develop clear leadership and organization. The success of Massachusetts companies and institutions to date is evidence that there is no lack of successful leadership within the life-sciences cluster. So far, however, that leadership has been focused mainly on the success of individual institutions, not on the success of the cluster as a whole. The recently created New England Healthcare Institute (NEHI) is a promising start. Nevertheless, there are still relatively few forums where CEOs from the cluster can interact regularly. Realizing the power of the network will require the dedication of time and energy to building relationships, infrastructure, and common organizations. It will also require coordinating a shared legislative agenda in those areas where interests overlap, and working closely with state government to develop a coherent strategy for the economic development of the cluster.

2. Improve networking and collaboration. The Massachusetts biotechnology industry has a long tradition of networking and collaboration, both among industry firms and between the industry and local academic institutions. The MBC itself has played a substantial and highly valuable role in encouraging collaboration. But as the life-sciences cluster has become larger and more complex, the costs of interaction have gone up. The cluster needs to invest in new mechanisms to encourage networking and collaboration.

Our interview subjects identified a number of areas in which more collaboration would contribute to the vitality of the cluster. Increasing interaction among companies, especially between the research facilities of big pharmaceutical companies and small biotechs, was frequently mentioned. Networking between industry and academia is also clearly an area in which there are significant opportunities for improvement. Both industry executives and academic researchers commented on the difficulty each sometimes has in identifying potential partners.

Finally, increased collaboration within and among Massachusetts universities and academic medical centers may be especially important in the years ahead. Federal funding agencies increasingly favor institutions that work together in collaborative research partnerships in order to avoid wasting scarce resources on redundant projects. Pooling the resources and creative talents of some of the best and brightest minds in the world could well improve the state's chances in the growing competition for federal research dollars.

But even more important, the very evolution of life-sciences research demands more collaboration. Increasingly, the most exciting and promising frontiers of research are on the interface between disciplines. One example is systems biology, which combines biology, computing, and systems engineering. Collaborative partnerships that match the state's extraordinary array of talent in the life sciences with its remarkable strengths in many related fields of science and engineering could be a winning combination that shapes the future direction of the entire life-sciences cluster.

There are any number of mechanisms that cluster members could use to improve networking and collaboration both within and across cluster segments. Some examples are:

- Regular partnering conferences
- Topic-specific mentoring panels
- Idea-exchange forums
- Web-based matching programs to help connect parties with complementary needs and interests
- Consortia to pool resources for infrastructure investments such as market research, technology platforms, or shared manufacturing space
- Industry-academic internships
- Cross-representation on company boards and academic advisory panels

But whatever the specific mechanisms, the life-sciences cluster must first commit to investing in its networking infrastructure and aggressively seeking out new areas for collaboration.

3. Create a more efficient operating environment. Maximizing the competitive advantage of Massachusetts also requires that cluster members work together to create a more integrated and more efficient operating environment. Three areas in particular would benefit from sustained attention:

3a. More transparent technology transfer. Improving technology transfer requires that cluster members increase the transparency of the processes involved. Universities and industry companies must communicate with each other regarding technologies available for licensing and desired types of licensing opportunities. In addition, both parties can work to streamline, standardize, communicate, and facilitate licensing processes to maximize their efficiency.



The evolution of life-sciences research demands more collaboration. Increasingly, the most exciting and promising frontiers of research are on the interface between disciplines.

3b. Streamlined clinical trials. Similarly, academic medical centers and industry companies can work together to standardize and streamline the clinical-trials process so that more trials are performed in local institutions. Keeping clinical trials in Massachusetts would benefit many segments in the cluster and could even become a core capability for specific players (for example, the University of Massachusetts Medical School).

3c. Collaborative work force development. Finally, members of the cluster should work together to forecast potential future shortages in the labor force. In a field as complex and fast-growing as the life sciences, it is highly likely that there will be shortages of specialists in key areas, which will either slow the drug-development process or increase its cost. Currently, no single group provides cluster members with a forecast of future labor shortages in key areas.

4. Increase coordination among clusterwide associations and initiatives. The various industry organizations that touch the cluster should coordinate their activities to ensure that they are pursuing complementary agendas and not using resources to pursue redundant activities. Similarly, the various cluster segments should identify where they have common legislative agendas and coordinate their lobbying activities whenever possible to increase the impact of their collective voice.

5. Commit to active public outreach. Finally, the cluster must commit time, energy, and resources to create an outreach program to build public confidence in biotechnology and to attract a higher share of life-sciences companies to Massachusetts. Massachusetts lags most competitive clusters in promotional efforts and should undertake a public relations campaign to promote its attractiveness to companies outside the state. The MBC can play a lead role in such an effort, but it can succeed only with the support and active participation of the entire cluster, acting as industry spokespeople and helping to spread the campaign messages and build key industry allies in state government.

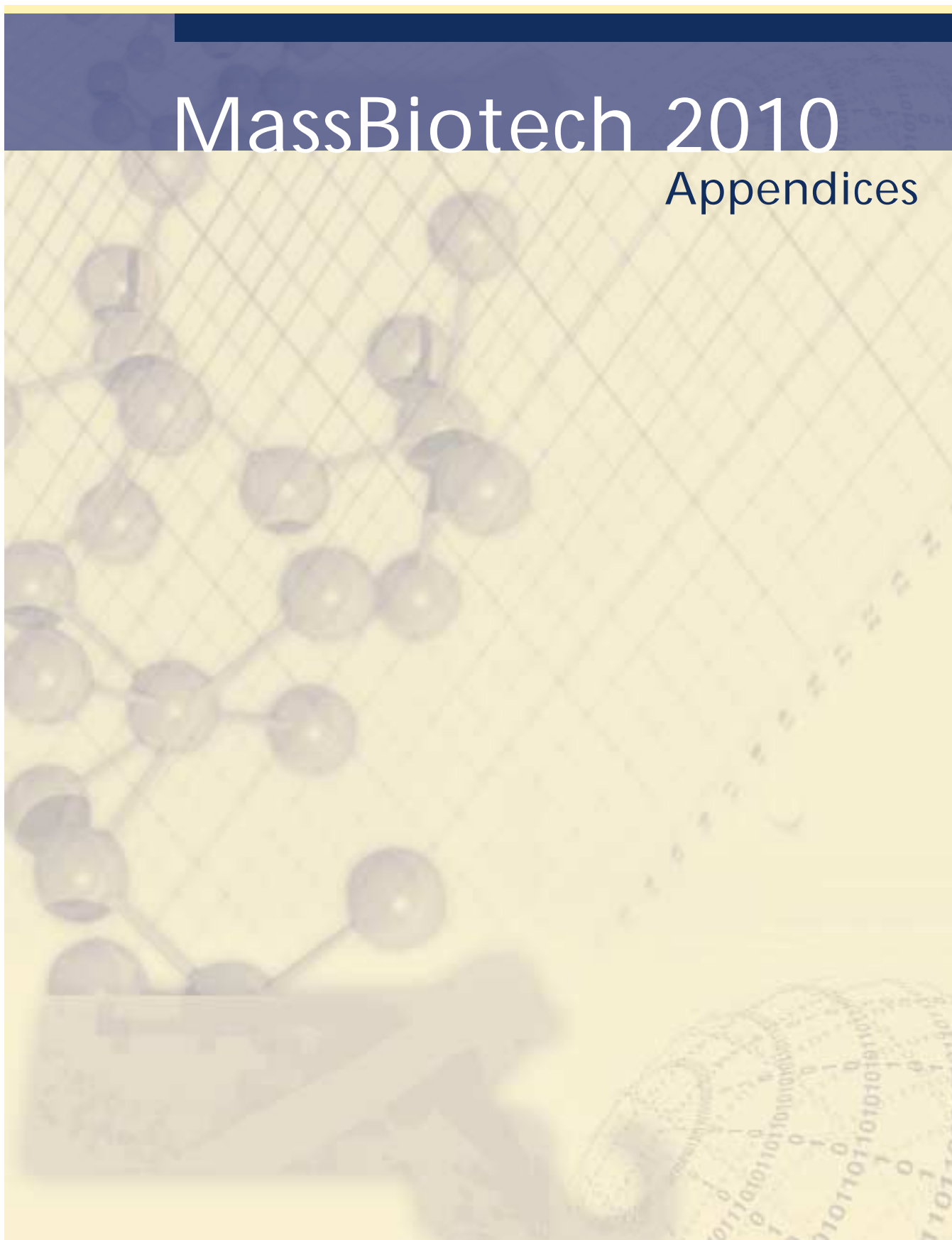
The MBC can also play a key role in working with the state to develop and carry out a policy that will support productivity and innovation within the life-sciences cluster. But tightening the cluster's cohesiveness and promoting collaboration are also essential to maximizing the quantity and value of the cluster's output. Direct participation by cluster members in promoting interactions and collaboration is essential to building an organizational architecture for the Massachusetts life-sciences cluster that will produce the type and quantity of breakthrough innovation required for global leadership.

Summary

The biotechnology industry and the entire life-sciences cluster have the potential to be a cornerstone of the state economy. The state's political, commercial, and academic leaders need to move quickly and decisively to capture for Massachusetts the advantage that has already been created. If they can find a way to do so, the rewards for the Commonwealth could be substantial. They could well make the difference between a state that is enjoying a sustained period of strong economic growth and one that is merely limping along. The difference in tax revenues would be sizable. Perhaps most valuable, the Commonwealth could continue its honorable tradition of being on the leading edge of technology, science, and health care, and of producing enterprises of which its citizens are justifiably proud. The MBC and its member companies are committed to helping realize this vision.

MassBiotech 2010

Appendices



APPENDIX I: SPECIFIC RECOMMENDATIONS OF THE MBC TOPIC TEAMS

To develop the policy recommendations for this report, the MBC created topic teams in the following nine areas:

- Business climate and infrastructure
- Financing
- Work force development and education
- Health care integration
- Biodefense
- Framework for innovation
- Tax
- Legal
- Regulatory

Each team consisted of four to six experts representing a wide range of organizations from the life-sciences cluster, including biotech companies, academic medical centers, institutions of higher education, health care providers, service organizations, and public and quasi-public agencies. This appendix lists the roughly 100 policy recommendations developed by the teams.

BUSINESS CLIMATE AND INFRASTRUCTURE COMMITTEE

Keep building the intellectual infrastructure to maintain Massachusetts leadership

- Invest in the state universities developing life sciences research and training programs
- Improve technology transfer from the state university system
- Support the NIH merit-based funding system
- Foster the three Ts (technology, talent, and tolerance) of a creative economy
- Maintain an open door for the international community to attract scientific talent and monitor immigration and visa requirements
- Invest in centers of excellence focused on breakthrough technologies to diversify the cluster and increase local biotech's share of federal grants
- Support diversity and the complementarities of numerous life-sciences research programs between public and private academic institutions

Plan the physical infrastructure to increase the attractiveness of Massachusetts

- Define a strategy for the growth of the biotechnology industry; identify new locations for development
- Undertake a long-term effort to work with the identified locations to ensure that all the infrastructure elements are present (public transportation, appropriate zoning regulations, etc.)
- Review and influence existing programs to enable biotech growth (e.g., Red Line to 128 in Mass Public Transport Plan, commuter rail station and zoning plans for the Alewife area)
- Strengthen Massachusetts as a global business center (convention center, Logan airport)
- Use smart growth principles to maintain the attractiveness of the Commonwealth and offer incentives to communities to support biotech development projects
- Preserve the quality of life and international flavor of the Boston area in order to allow the cluster to retain a highly qualified work force as well as attract top talent and entrepreneurs from around the globe
- Improve housing access through public transportation investments that unlock the potential of hard-to-reach communities and make commuting easier (e.g., North-South rail link)

Capitalize on the biotech manufacturing opportunity

- Capitalize on the fact that local companies will prefer to locate their first manufacturing facility close to their R&D facilities
- Offset an unfavorable federal tax structure versus Ireland or Puerto Rico with an advantage in speed-to-market
- Target local companies with products in clinical development and actively solicit them to locate their manufacturing facilities in Massachusetts
- Retain expedited permit review by the Department of Environmental Protection for significant biotech projects and, through legislation, enable municipalities to "opt in" to streamlined review and permitting process to make them more attractive to new biotech development
- Develop biotech opportunity zones in areas attractive for manufacturing and development activity
- Offer a selection of "pad-ready" sites with established power, sewage, road access, and biotech regulatory permits
- Ensure adequate supply and high reliability of energy and encourage improvement of energy distribution system to reduce costs
- Continue funding and improve the approval process for Public Works Economic Development Grants and Community Development Action Grants

FINANCING COMMITTEE

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Improve the climate for private investors

- Issue state general obligation bonds to fund major infrastructure developments for nonprofits and academic research centers (this could lead to more federal funding for Massachusetts, which could generate more intellectual property available for investment)
- Keep current tax incentives and market a deferral-of-capital-gains advantage for early-stage private investors
- Retain and promote the mutual fund industry in Massachusetts

Encourage improvements in existing state programs

- Allow the sale of tax credits generated by biotech to provide capital (see Tax committee)
- Recapitalize the Emerging Tech Fund to provide leasehold improvement loans (currently, biotech companies use substantial cash for leasehold improvements; these loans will help developers bear the one-time capital cost, which will be recovered in the rent)
- Encourage state pension funds and other public investment funds to invest in start-ups and early-stage venture capital funds, under the rubric of prudent allocation to alternative investment (thus allowing Massachusetts to compete with states such as California, North Carolina, and Wisconsin)
- Encourage participation by fund managers in industry-sponsored investor conferences
- Update charters of public-purpose agencies to facilitate investment in Massachusetts biotech—in particular, that of the Massachusetts Capital Resource Company (MCRC) and the Massachusetts Business Development Corporation (MBCD)

WORK FORCE DEVELOPMENT AND EDUCATION COMMITTEE

Increase science exposure for all Massachusetts students

The state must ensure that its students are exposed to the life sciences in a way that increases their interest and competence so that they will appreciate biotechnology and take advantage of its future growth opportunities.

- Require a science curriculum coordinator in all elementary schools
- Empower and offer support and resources to motivated science teachers
- Establish a science requirement and/or four years of science for graduation
- Provide a governor's excellence-in-science grant for top schools and those that improve most in exposing a broad range of the student population (from vocational to AP classes) to the opportunities and advantages offered by life-sciences education; offer technical assistance for schools that lag in meeting these goals
- Create a program for "science infusion" at public universities, even for nonscience majors
- Encourage cross-pollination between industry and academia through internships for professors and scientists giving lectures and teaching specific topics at universities
- Offer professional development and continuing education opportunities to K-12 teachers

Ensure that schools have adequate lab facilities and supplies

- Develop tracks for biotech careers
- Develop homegrown talent for all types of biotech careers to supplement talent from around the world.
- Develop programs outside traditional bachelor of science and postgraduate degrees, such as vocational and high school biotech training programs, introduction to biotech certificate programs, community college programs for lab and manufacturing technicians, and specialist programs for manufacturing and clinical development
- Develop financing mechanisms for mid-career switch to biotech programs, offering state loans for employees not covered by an employer

Empower state, academia, and industry advisory board to lead the science education agenda

- Establish a science advisory board that will appoint task forces with representatives from government, academia, and industry to implement change at all levels of the education system
- Empower the science advisory board to define the priorities, identify curriculum synergies across the different systems, and ensure that initiatives are coordinated

HEALTH CARE INTEGRATION COMMITTEE

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Massachusetts has the opportunity to create a model health care financing and delivery system. This system, based on sound fiscal principles, needs to provide quality care and access to innovative technology while assuring adequate reimbursement of product and service providers.

Reward innovation

- Educate professionals and the public on the benefits of breakthrough technologies
- Encourage health care plans—including Medicaid—to strengthen technology assessment processes so that innovative products become quickly available to patients once approved by the FDA and accepted for coverage by the plan
- Encourage participation in clinical trials by providing systematic reimbursement benefits

Enable access to new technologies

- Expand programs such as Prescription Advantage by pulling in federal dollars (Prescription Advantage is based on the right principles: actuarially sound, means tested, privately run)
- Encourage coverage policies that allow recognition of innovative products and look to short- and long-term results and outcomes (centralized and inflexible coverage and payment systems slow innovation and enshrine traditional, outmoded therapies)
- Assess technology in light of total system costs, including all short- and long-term savings, when evaluating innovative products (as opposed to simply comparing drug costs from year to year)

Enforce market-based principles

- Set drug pricing by means of negotiated processes
- Avoid price controls and inadequate reimbursements, which stifle innovation and create market distortions and inefficiencies in all segments of health care delivery, including therapeutics, physician care, hospitals, and nursing homes
- Encourage financing systems with appropriate and fair levels of cost sharing, which will help the system become more consumer-driven and efficient while giving patients access to additional beneficial therapies
- Offer patients more options to reduce spending by enabling the decision makers to opt out of less efficient treatments

BIODEFENSE COMMITTEE**Work with the industry and state legislature on biodefense regulation**

- Include industry, through the MBC, in drafting legislation on biopreparedness and emergency measures
- Notify industry about compliance procedures for specific biological agents through the MBC

Create a consortium to respond to biothreats

- Partner with the industry to demonstrate to the public that biotech is a valuable resource for Massachusetts in the event of a bioterrorist attack or other public health emergency
- Develop with industry a biopreparedness consortium consisting of biotech companies willing to dedicate resources (for example, compound libraries, sequencing capability, lab facilities, or pharmaceutical materials) in the event of a bioterrorist event or other public health emergency; the consortium will contract with the the Department of Public Health (DPH) to facilitate effective assistance to the state and establish legal safeguards before a crisis occurs

Work with government agencies on R&D opportunities in biodefense

- Include the biotech industry in the DPH work groups focusing on homeland security, so that biotech companies have the opportunity to develop solutions based on their expertise
- Develop joint DPH and industry collaborations to increase critical federal funding for Massachusetts
- Use the DPH as a conduit for confidential subject referrals for clinical trials
- Encourage the DPH, UMass, and/or the state laboratory to work with industry to create state or federally indemnified programs to advance critical biodefense-related medical research
- Create public-private partnerships to accelerate the development of biodefense solutions, including potentially working and partnering with the Massachusetts Antiterrorism Task Force (ATTF)
- Explore commitment to a market for products developed in support of a National Pharmaceutical Stockpile to increase industry incentives and participation
- Increase the effectiveness of federal and state government-relations functions
- Adequately staff a Washington-based Massachusetts federal-state government relations office to secure more federal biodefense R&D funding for Massachusetts companies and institutions
- Work with the MBC to understand positions and initiatives that would enable the biotech industry to provide solutions to key biodefense needs

FRAMEWORK FOR INNOVATION COMMITTEE

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Update the framework for innovation

In the early days of biotech, the industry and local communities created a world-standard framework for innovation. With the rapid advance of science, the state needs to provide a predictable, fair, and transparent regulatory environment that offers stability and certainty for the industry.

- Use scientific principles, not precautionary ones, in advancing science and innovation
- Give all research facilities and biotechnology companies the right to conduct business within the legal framework

Strengthen public support and trust

The industry has gained public support by being a good neighbor in its community.

- Promote and support educating the public on the benefits of health care and biotechnology
- Support industry, academic institutions, and the public by organizing a robust and transparent process to address, as a community, the controversial issues associated with cutting-edge research in the life sciences
- Recognize the vital importance of appropriate animal testing, in full compliance with current regulations and professional standards, for the Massachusetts research community, and work with the life-sciences community to address the public's concern about animal research
- Support the industry in explaining the positive environmental impact of biotechnology
- Enhance patient safety and participation in clinical trials by strengthening the internal review boards regulation and process in the state

Encourage diversification of the cluster

- Set up the next generation of centers of excellence with a focus on strong areas for Massachusetts, e.g., biocomputing, biodefense, and nanotechnologies
- Explore opportunities in biomaterials, bioremediation, marine aquaculture, and space-related innovations in therapeutics and devices

TAX COMMITTEE**Maintain stability and predictability in the Massachusetts tax system by protecting reforms enacted since 1991**

- Retain the single sales factor apportionment regime for manufacturers
- Retain research and development credits
- Make investment tax credits permanent at the current 3 percent rate
- Maintain the 5 percent sales tax rate

Increase the effectiveness of existing tax incentives

- Enable start-up companies to sell tax attributes, including research and development and investment credits and net operating loss carryforwards, to unrelated parties, so that the value of these benefits can be used as capital during the start-up phase
- Revise the definition of a Massachusetts research and development corporation to make it more likely that the definition will apply to start-up companies
- Broaden the sales-tax exemption for manufacturing equipment to include equipment incorporated into a facility by a construction contractor
- Define expenditures eligible for the Massachusetts research and development credit to include expenditures related to national clinical trials that are managed from Massachusetts
- Expand the local and state tax benefits associated with the Economic Development Incentive Program
- Expand the sales tax exemption for manufacturing materials to cover bricks-and-mortar expenditures
- Permit the Massachusetts investment tax credit to be used by all members of a Massachusetts “combined” corporate group

Use tax policy selectively to promote and enhance the competitive climate for biotechnology companies in Massachusetts

- Adopt environmental tax incentives to encourage the creation of cost-effective facilities that promote a cleaner environment and healthier workplaces
- Adopt job creation tax credits or accelerated deductions for salary expenses
- Adopt the federal position liberalizing the rules for using loss carryforwards and other favorable tax attributes in mergers and acquisitions

LEGAL COMMITTEE

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Tort reform: Remain vigilant to prevent any potential insurance market breakdown

Currently, winning a product liability trial in Massachusetts requires a considerable burden of proof, though some settlements have taken place. Although insurance premiums have increased significantly, market-based mechanisms are in place and have prevented any breakdown to date. So far, private insurers have not pulled out of the market or imposed conditions that would bring the health care system to a halt.

- Remain extremely vigilant, as Massachusetts with its strong base of health care providers and industry would be deeply hurt by any such breakdown, whether it relates to medical or product liability
- Cap responsibility for malpractice and adverse effects much as California and Utah have done recently

Clinical-trial liability: Explore legislation to tackle the problem

Clinical-trial liability is outside the scope of the tort system, since the product under trial is still being tested. One of the goals is to uncover potential adverse effects from the product during the clinical trial. Specific recommendations are listed below to ensure that clinical-trial activity in Massachusetts remains strong.

- Regulate clinical trials under a no-fault system
- Provide state indemnification by creating a mechanism such as a fund to compensate patients exposed to adverse events for clinical trials not covered by federal contracts

Controversial issues related to science and technology: Do no harm

- Recognize the role of the FDA, the EPA, and the USDA in regulating the biotech industry and in providing frameworks for these issues
- Maintain the well-established legal framework already in existence for environmental-damages lawsuits

REGULATORY COMMITTEE

Regulatory Committee

Several operational and strategic opportunities exist to enhance the competitiveness and growth of the biotech industry in Massachusetts. The following recommendations focus on environmental, public health, and safety regulations.

Operational focus: Continue to support streamlined and performance-based regulations

- Support and expand self-certification of regulatory compliance when appropriate (for example, the Department of Environmental Protection's Environmental Results Program has simplified the permitting and reporting process and minimized the paperwork burden through performance-based regulations and self-certification; this flexible approach gives environmental agencies the opportunity to focus limited staff and resources on environmental priorities and allows biotech companies to focus resources on better ways of protecting human health and the environment)
- Establish an industry working group with key agencies, such as the DEP, the Executive Office of Environmental Affairs (EOEA), the Department of Public Safety (DPS), and the Department of Public Health (DPH) to review specific regulations that may be obsolete, identify opportunities to streamline or integrate similar requirements originating from different agencies, and explore "beyond-compliance" initiatives
- Explore meaningful incentives (e.g., fast-track permitting, tax incentives, flexible guidance) that would encourage industry to improve environmental management
- Allow compliance with some regulations to be certified by independent auditors in order to speed up the permitting or approval process

Strategic focus: Take and encourage responsible positions on specific emerging biotechnology issues by effectively using the existing federal regulatory model (e.g., guidance and local oversight committees)

- Provide forums for science-based discussion of biotechnology issues, focusing on science-based regulation and risk management, multiagency working relationships, and stakeholder participation
- Educate political leaders about the presence and function of local oversight committees composed of scientists, physicians, and community representatives involved in the necessary decisions concerning genetic engineering (for example, the Institutional Biosafety Committee), animal welfare (the Institutional Animal Care and Use Committee), and human subject experimentation (the Institutional Review Board).
- Promote the above boards as successful models of scientific, democratic, and responsive decision making and apply them to new technologies in the future
- Create decentralized, informed, and representative decision-making bodies to avoid inappropriately broad and sweeping regulation in addressing biotechnology's rapidly evolving science and ethical considerations

APPENDIX II: MASSBIOTECH 2010 STAKEHOLDERS

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